248408-M June 2003



SYNCHRON CX® Clinical Systems

For *In Vitro* Diagnostic Use Operating Instructions

This manual is intended for use with SYNCHRON CX®4/CX®7 DELTA SYNCHRON CX4/CE/CX7 SYNCHRON CX7 RTS/CX9 ALX SYNCHRON CX®4 PRO/CX®7 PRO/CX®9 PRO

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IMPORTANT NOTES TO THE OPERATOR FOR SYNCHRON CX® DELTA VERSION 4.0 THROUGH 4.6 SOFTWARE

PURPOSE These notes serve to advise the operator of important information necessary for the successful operation of the SYNCHRON CX® DELTA Version 4.0 and greater Systems. NOTE 1 PRINTER SET-UP WITH VERSION 4.0 INSTALLATION The printer must be set to Epson FXe Emulation Mode and Character Set II to support the print commands for the SYNCHRON CX[®] DELTA version 4.0 and greater software. Refer to Section 5.1.2.1, "Setting Emulation Mode and Character Set," in the CX4/CX7 and CX5 Operating Instructions Manual. NOTE 2 QC ARCHIVE RETRIEVAL FROM PRE-VERSION 4.0 QC DATA Retrieval of precision and accuracy flags with QC data from pre-version 4.0 archived diskettes may take up to 20 minutes, due to formatting changes to QC data storage in version 4.0 and greater. When retrieving this QC data, the operator will be given the option of whether or not to retrieve the precision and accuracy flags. By not retrieving these flags the total retrieval time will be significantly reduced. NOTE 3 CX4 REAGENT LOCATION AND VERSION UPGRADE Due to changes to information storage in Version 4.0 software, CX4 reagent location from pre-version 4.0 data (version upgrade) will not be printed on the laboratory format reports.

NOTE 4 INSTRUMENT INTERRUPTION OF REAGENT LOAD WHILE RUNNING

If the system interrupts Reagent Load While Running with instrument errors, such as motion, printer, or host errors while the instrument status is "Pending Reagent Load," the operator should go to the Reagent Load Screen and press **F1 CANCEL LOAD.** It is important to Cancel Reagent Load before the pending load time counts down to zero to avoid the need to press **EMERGENCY STOP** at an inopportune time in testing.

NOTE 5 "@" SYMBOL FOR FIELD OVERFLOW

The "@" symbol is used to indicate that the information in the field is too long for the allotted field length. This occurs when a control data point is deleted. The results recall screen for that control will display the "@" symbol in the remarks column instead of "QC RESULT DELETED."

NOTE 6 SUPPRESSED RESULTS AND THE EDIT FUNCTION

Version 4.0 and greater software allows the editing of suppressed results. If a suppressed result is edited and the operator decides to restore the original suppressed status by pressing **F4 RESTORE RESULTS**, the operator must then press **F3 UPDATE REMARKS** to reinsert the SUPPRESSED comment. **PREV SCREEN** to the RECALL Screen will also correctly insert the comment. The operator should <u>never</u> use the Editing Screen to report clinical results, as this screen may or may not be fully updated depending on the actions of the operator. Use the RECALL Screen to display results for reporting.

NOTE 7 PANEL SELECTION IN QC BY REAGENT CARTRIDGE SAMPLE PROGRAMMING

When the system is set to program Quality Control by reagent cartridge position, selection of a panel from the PANELS window will cause the system to lock up. If this occurs, the system must be rebooted and the affected QC sample program must then be cleared after rebooting. To avoid the system lock-up, the operator should enter the panel number in the "Panel:" field of the sample programming screen, or move the cursor to the appropriate chemistries and press **SELECT**. Do not enter the panel number while in the PANELS window through **F1 SELECT OPTIONS**. The operator may refer to the PANELS window as long as no selections are made while the window is open. **PREV SCREEN** out of the window and then make the selection while in the Panel field.

NOTE 8 AUTO CLEAR QUEUE

NOTE 9

If the auto clear queue function is turned on in Host Communications, it is possible for the same patient sample to be rerun unintentionally and new results be sent to the host, depending on the operation of the host. If a patient sample is run and the status is complete, and that sample is reloaded, the patient sample will be cleared from the queue and the host will be queried for programming for that sample. The auto clear queue function is only available when the host is in bidirectional mode, host query is enabled, and barcode mode is enabled.

CALIBRATION VERIFICATION AND LINEARITY

The system must be in STANDBY/STANDBY to access **F1 DEFINE REVIEW** or **F2 DELETE SET** in the Calibration Verification and Linearity function. A fatal error may occur if the operator should access these softkeys and answer "**Y**" to the confirmation message while the system is running. Should the fatal error occur, a reboot of the system is necessary to restore system operation.

NOTE 10 CALIBRATION MANUAL CUP ASSIGNMENTS

Clear all calibration manual cup assignments after each calibration. If this is not done, the same calibration ID will not run if it is loaded on the system for a subsequent calibration run.

NOTE 11 LOST ADMINISTRATOR PASSWORD

It is important to store the edited Administrator password for the Password Access function in a secure location. Should the Administrator password be forgotten or misplaced, it will be necessary to have a Service Representative retrieve the password; or, the customer will have to reload Version 4.0 software.

NOTE 12 ISE CALIBRATION

Due to the analyte selectivity of each ISE electrode, it is necessary to correct for the concentration of common serum and urine constituents. In order to obtain an acceptable result, two conditions must be met: a) a successful calibration of one or more analytes and b) the measurement of one or more analytes with the result in the analytical range for the sample type. * Chemistry results are used in the calculation of analyte requested, however, programming of chemistry is not necessary. The following table is a summary of the calibrations and results that are required when running the various ISE chemistries.

ANALYTE REQUESTED		CALIBRATION REQUIRED				RESULT REQUIRED*		
		NA	K	CL	Ca	NA	K	CL
NA	SERUM	YES	YES				YES	
	URINE	YES	YES				YES	
K	SERUM		YES					
	URINE		YES					
CL	SERUM			YES				
	URINE			YES				
CALC	SERUM	YES			YES	YES		
	URINE	YES	YES		YES	YES	YES	

NOTE 13 WAITING/WAITING

The system may occasionally go into a WAITING/WAITING state to avoid situations requiring reboot. When this occurs, press the emergency **STOP** softkey and then **SYS HOME**.



This safety notice summarizes information basic to the safe operation of the SYNCHRON CX® System described in this manual. The international symbol displayed above is a reminder that all safety instructions should be read and understood before installation, operation, maintenance, or repair of this instrument. When you see the symbol on other pages, pay special attention to the safety information presented. Observance of safety precautions will also help to avoid actions that could damage or adversely affect the performance of the instrument.

Other symbols may also be displayed on the equipment. These are reproduced and described in the Operating Precautions and Hazards section.

Safety During Installation and/or Maintenance

This instrument is designed to be installed by a Beckman Field Service representative. Installation by anyone other than authorized Beckman personnel invalidates any warranty covering the instrument.

Any servicing of this equipment that requires removal of any covers can expose parts which involve the risk of electric shock or personal injury. Make sure that the power switch is turned OFF and that the instrument is disconnected from the main power source. Refer such maintenance to qualified service personnel.

Electrical Safety

- To reduce the risk of electrical shock make sure that the matching wall outlet receptacle is properly wired and earth-grounded.
- Never remove or install any circuit board, connect or disconnect any plug or cable, while the power
 is ON. Always use the antistatic wrist strap located in the electronic board compartment when
 removing or installing any circuit board.
- Do not place containers holding liquid on top of the instrument. If a spill occurs, liquid may get into the instrument and damage electrical or mechanical components.

Safety Against Risk of Fire

Fuses protect certain electrical circuits within this instrument against overcurrent conditions. For continued protection against the risk of fire, replace only with the same type and rating specified.

Mechanical Safety

For safe operation of the equipment, observe the following:

- Operate the system with reagent door and covers and shields in place.
- During power up, routine operation, and diagnostic procedures, keep hands and/or foreign objects out of the path of the sample carousel and sample and reagent probes.
- Do not attempt to clean around the sample carousel and sample and reagent probes while they are in motion. Wait until the instrument is in "standby" to perform cleaning procedure.

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Chemical and Biological Safety

Normal operation may involve the use of solutions and test samples that are pathogenic or infectious. Observe all laboratory policies or procedures which pertain to the handling of these materials.

- The reagents and other chemical preparations used with the system will not normally cause adverse reactions; however, those persons with sensitive skin should wear protective gloves before attempting to work with reagents and other chemical preparations.
- Do not handle sample or solutions without proper protection. Body fluids and other infectious samples must be handled according to good laboratory practice to prevent spread of disease.
- When performing maintenance, service, or troubleshooting on elements of the system that have contacted sera or other biological fluids, observe standard laboratory precautions. It is always necessary to wash your hands thoroughly after performing any routine maintenance.
- Dispose of all waste solutions according to appropriate environmental health and safety guidelines.

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Section 1 GENERAL INFORMATION

1.1 INTENDED USE

The Beckman SYNCHRON CX4 DELTA, CX7 DELTA, CX4CE, and CX7 systems (Figures 1-1, 1-2) are fully automated and computer controlled instruments designed for the in vitro diagnostic quantitation of biological fluid components and therapeutic drugs as well as the qualitiative determination of drugs of abuse in urine.

The CX4 DELTA and CX4CE both provide the capability of performing 24 photometric chemistry determinations, using positive sample ID, primary tube sampling and host query. In addition to a difference in the color and shape of the instrument panels and covers, these two systems operate with different sector bar code readers.

The CX7 DELTA system adds a CX3 module to the CX4 DELTA for STAT determination of sodium, potassium, chloride, calcium, CO₂; all of which are measured with ion-selective electrodes. In addition, Glucose, Creatinine, Total Protein, and BUN (or Urea) cup chemistries are offered.

The CX7 system adds a CX3 module to the CX4CE for the STAT determination of sodium, potassium, chloride, CO₂; all of which are measured with ion-selective electrodes. In addition, Glucose, Creatinine, Calcium, and BUN (or Urea) cup chemistries are offered.



Figure 1-1. Beckman SYNCHRON® CX7 DELTA System

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Figure 1-2. Beckman SYNCHRON® CX7 System

1.1.1 Scope of This Manual

This manual covers clinical measurements as they pertain to the operation of the SYNCHRON CX Systems and makes no attempt to instruct the laboratory technologist in clinical diagnosis. Medical and diagnostic interpretation or the clinical significance of the assay results provided by the system are not discussed. Typical and actual results are shown only to demonstrate the operating procedures, parameters, and characteristics of the system.

This manual includes operating instructions for the CX4 DELTA, CX4CE, CX7 DELTA and CX7 systems. Since this manual represents both systems, and the appearance of each system is unique, some figures in this manual show instruments which appear different from the instrument in your laboratory. References to the CX7 DELTA include the CX4 DELTA and CX3 DELTA while references to the CX7 include the CX4CE and CX3. Throughout the text, unless otherwise noted, references to the CX7 will pertain to BOTH the CX7 and CX7 DELTA, while references to the CX4 will pertain to both the CX4CE and the CX4 DELTA systems. Information specific to a system will be noted. The following paragraphs briefly describe the contents of each major section of the manual:

Section One: provides general information about the SYNCHRON CX Systems. Among the topics covered are warranty and service policy, telephone service information, performance specifications, and labels and symbols.

Section Two: contains the requirements and procedures necessary for installation.

Section Three: contains information on the hardware modules of the instrument. A detailed description of the individual components is presented.

Section Four: contains information on the principles of operation. This section provides a basic overview of the principles of photometric measurements employed on the instrument, as well as a fundamental explanation of sample and reagent flow through the system. A discussion of the electrolyte (and Ca ISE) and STAT chemistry (CX3 BUN, Glucose, Creatinine, and Calcium Cup or Total Protein) methodologies is also included.

Section Five: provides a thorough explanation of how an operator interacts with the instrument. For example, this section includes a detailed description of the operation software, printer setup, proper diskette handling, etc.

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Section Six: provides step-by-step instructions for use of each major operator software feature. Screen examples are provided along with the instructional text to illustrate the particular procedure.

Section Seven: presents quality control information and instructions for using the on-line Quality Control programs.

Section Eight: presents information on user-defined chemistries.

Section Nine: presents maintenance procedures.

Section Ten: contains the host interface specifications.

Section Eleven: lists the operating precautions and hazards.

Section Twelve: provides information regarding specific part numbers.

Appendices: contains the appendices referenced in the manual.

Index: provides a convenient cross-reference index of all sections. This index can be used as a quick method of locating a specific topic in the manual.

1.2 WARRANTY AND SERVICE POLICY **INFORMATION**

The SYNCHRON CX Systems are covered by and subject to the exceptions of the standard warranty enclosed with each system. They are warranted against defects in the material or workmanship for one year. The warranty period is to commence on the day of delivery to the original purchaser by Beckman Instruments, Inc., or authorized representative.

1.2.1 **Responsibility During the Warranty Period**

The operator has the responsibility for the routine preventive maintenance procedures included in this manual (see Section Nine). Repairs arising from failure to perform these maintenance procedures at the time intervals indicated will be made at the users' expense.

1.3 TELEPHONE SERVICE

For U.S.A. and Canadian customers only:

Call your local Beckman office toll-free from anywhere in the continental United States, Alaska, Hawaii and Canada at (800) 854-3633. The purpose of the Beckman 24-hour/7-day telephone service is to allow you to contact trained Beckman personnel to receive assistance with operational and service questions.

For International customers only:

If any fault develops in your system, call the nearest Beckman Field Service Office. Office phone numbers are listed in Appendix A.

1.4 SYMBOLS AND LABELS

The following is a list of symbols and labels used on the SYNCHRON CX Systems:

Protective Conductor Terminal



Printer



Video Display Terminal



Main Power On



Main Power Off



Printer/Terminal Power On



Printer/Terminal Power Off



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Signal Input



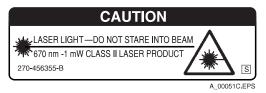
Sample Bar Code Reader



Sample Bar Code Reader



Sample Bar Code Reader



Carousel Covers (3)



A_00566C.EPS

Carousel Covers (3)



1.5 PERFORMANCE SPECIFICATIONS

Table 1-1, beginning on the next page, lists the performance specifications for the SYNCHRON CX4/7 Systems.

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SAMPLING SYSTEM

Sample volume per test: 3 to 30 µL except electrolytes; Na, K, Cl and CO₂ and CALC (ISE) are

performed on a total volume of 62 µL.

Sample processing rate: Sample dispensed every 16 seconds on the CX4 and every 48

seconds on the CX3 portion of the CX7

Throughput: CX4 - up to 225 tests per hour

CX7 - up to 825 tests per hour

CX7 DELTA - up to 900 tests per hour

REAGENT DELIVERY SYSTEM

Reagent volume per test CX4 - 200 to 327 μL

CX7 - 200 to 327 µL for cartridged chemistries, 0.22 mL to 1.25 mL

reagent and 6.87 mL wash solution for bulk reagents.

Reagent processing rate: CX4 - Reagent dispensed every 16 seconds

CX7 - Reagent dispensed every 48 seconds

Onboard reagent storage: CX4 - 24 refrigerated (2-8°C) positions (1-24)

CX7 - 24 refrigerated (2-8°C) positions (1-24) and 8 room-temperature

positions on CX3

Onboard reagent stability: 30 days once opened (except for the following chemistries with

indicated expiration dates):

Days Chemistry **Days Chemistry** 5 ALT-, AST-, CKMB ALC, MG 7 ALP 10 14 LAC, LIPA, PAMY, SAL CK-, GGT 20 CREA, CR-T, TP 21 42 CAR, CHE, GEN, PHE, 60 Electrolyte Buffer, AMPH, PHY, THE, TOB ASO-, BARB, BENZ, 90 CO_2 COCM, CRP, METD, METQ, OP, PCP, PROX, RF, THC, THC2, THC5

Cartridge volumes: A - 110 mL, B - 18 mL, C - 4 mL

PHOTOMETER SYSTEM

(CX4 chemistries, positions 1-24)

Type: Multi-wavelength, diffraction grating spectrophotometer

Light source: Pulsed xenon lamp

Detector: Discrete photodiodes in fixed array

Available wavelengths (in nm): 340, 380, 410, 470, 520, 560, 600, 650, 670, 700

Half bandwidth: $5nm (\pm 2 nm)$

Absorbance range: 0.0 to 1.5 A operating range

0.1% optical linearity in a 1.5 A range 0.5% electronic linearity in a 1.5 A range

0.0004 A maximum noise at 0 A

Cuvette path length: 0.5 cm

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Table 1-1. Performance Specifications (Continued)

CUVETTE REACTION SYSTEM

(CX4 chemistries, positions 1-24)

Operating temperatures: 30°C or 37°C (operator-selectable)

Temperature accuracy: ± 0.1 °C

Temperature regulation: ± 0.1 °C

CX3 MODULE (CX7 only)

Measurement principle: Ion-selective electrodes for Na, K, Cl, CO₂ and CALC (ISE);

colorimetry for CRE3 and CA3 (or TP3); conductivity for BUN3 and

oxygen depletion for GLU3.

Measurement time: 48 seconds (all eight or nine tests)

Reagent type: Na, K, Cl, CALC (ISE) - ISE Electrolyte buffer, Wash solution, ISE

Electrolyte reference

CO₂ - ISE Electrolyte buffer, Wash solution, ISE Electrolyte reference,

CO₂ acid reagent, CO₂ alkaline buffer

BUN3 - Urease reagent and wash solution
CRE3 - Creatinine reagent (Alkaline Picrate)
GLU3 - Glucose oxidase and wash solution

CA3 - Calcium reagent (Arsenazo)
TP3 - Total Protein reagent (Biuret)

Reagent volume per test:

Na, K, Cl, CO₂, CALC (ISE): 0.81 mL ISE Electrolyte buffer

6.87 mL Wash solution

1.00 mL ISE Electrolyte reference

0.65 mL CO₂ acid reagent (CO₂ alkaline buffer recycled)

CX3 onboard reagent storage: Room temperature

Minimum sample volume*:

Sample Cups	0.5 mL	2.0 mL
GLU3	110 μL	150 μL
CA3, TP3 (serum), BUN or CRE3 (1 only)	80 μL	150 μL
TP3 (CSF)	160 μL	160 μL
GLU3, CL, TP3 (all CSF)	-	250 μL
Electrolytes (any/all)	110 μL	275 μL
All CX3 Chemistries (serum)	210 μL	300 μL
CX4 Tests	40 μL	175 μL

^{*} Minimum volume required for accurate level sensing is dependent upon the sample container used and the test panel. Please refer to Paragraph 11.1.2 for detailed information.

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Section 2 INSTALLATION

2.1 INSTALLATION POLICY

When you receive your SYNCHRON CX System, please notify your local Beckman Sales and Service office (refer to Appendix A). At this time a Beckman Service Representative will be assigned to supervise unpacking. Your representative will also perform the installation and prepare the system for initial use.

2.2 SHIPPING DAMAGE

Each SYNCHRON CX System is carefully examined and checked by Beckman before it is shipped. When you receive your new SYNCHRON CX System, visually inspect the shipping container for any possible damage. If there is damage, notify the Beckman Service Representative before his/her arrival at your facility to install your system.

If no damage is found to the shipping container, the Beckman Service Representative will supervise the unpacking of your system. If it is damaged in any way, the customer should file a claim with the carrier. If no damage is found, a visual and operational check of your system will be performed.

If any fault develops in your system, call the Clinical Support Center (North American Customers call 1-800-854-3633); International customers, call your local Beckman office and give full details of the difficulty. Be sure to have the model number, part number, and serial number.

2.3 SYSTEM POWER REQUIREMENTS

The system can operate from any standard 3-wire electrical outlet and is wired as shipped from the factory to operate on 220 V AC, 50/60 Hz.

NOTE

Line voltage from the electrical outlet should be free of spikes, fluctuations, and dropouts for protection of the electronic circuitry.

CAUTION

Operate system from 3-wire power source only. DO NOT use 2-prong adapters or a 2-wire AC power source. Your Beckman Service Representative will inspect your facility and recommend the best methods for connecting the system.

2.4 OPERATING SITE SELECTION AND PLACEMENT OF EQUIPMENT

Select an area in the laboratory that allows an 18-inch (46.0 cm) clearance at the rear of the system, so that exhaust and intake fans will operate efficiently. Allow at least 30 inches (76.0 cm) clearance on the right side of the system. Also, allow at least 12 inches (30.0 cm) clearance above the unit. The instrument should be located near a sink or drain to accommodate the waste effluent at a minimum rate of 7 liters/hour. Do not place the unit in direct sunlight or in drafts.

CAUTION

All waste liquids from SYNCHRON CX Systems should be disposed of in the approved method for handling biological contamination.

2.4.1 Leveling Procedure

Leveling screws are provided on the corners of the instrument, and should be used to adjust the instrument until the reaction carousel is level ($\pm 5^{\circ}$). The surface on which the unit rests must be free of vibration, especially from nearby equipment such as centrifuges.

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2.5 SECTOR LABELS

The sectors provided with the system require that only the identifying bar code label (1-60) be applied before use. Please refer to section 2.5.1 for CX4/CX7 DELTA systems and section 2.5.2 for CX4CE and CX7 systems. If a sector must be labeled to work on both CX DELTA systems and CX4CE/CX7 systems, refer to Figure 2-4 for placement of both types of sector bar code labels.

2.5.1 CX4/CX7 DELTA Sector Labels

Each sector will have four labels:

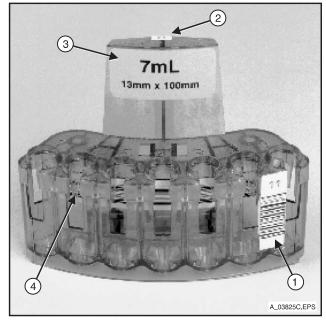
- Sector identification bar code label for front of sector
- 2. Small corresponding numeric label
- 3. Colored label indicating tube size
- 4. Background bar code label to identify empty tube positions

Replacement labels are available to replace damaged ones.

- Place the sector bar code label so it is centered between cup positions one and two of the sector. The top of the label must be even with the upper edge of the sector base (Figure 2-1). Smooth out any wrinkles or air bubbles which may appear.
- Place the small numeric label square to the smooth marking on the top of the sector (Figure 2-1). This allows for easy identification of the sector while on the sample carousel.
- 3. Verify that each sector is being identified correctly by performing the Sector Reader Test (See Diagnostics and Troubleshooting Guide, Paragraph 3.5.4.3).

NOTE

If a label must be replaced, remove the old label prior to applying a new one.



- 1 Sector Bar Code Label
- 2 Small Numeric Label
- 3 Colored Label Indicating Tube Size
- 4 Background Bar Code Label

Figure 2-1. CX4/CX7 DELTA Sector Labels

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2.5.2 CX4CE/CX7 Sector Labels

Each sector will have four labels:

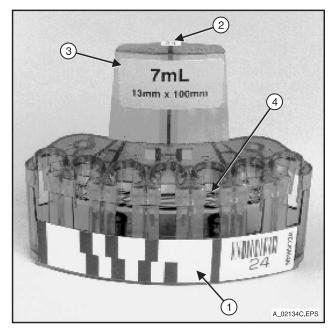
- Sector identification bar code label for front of sector
- 2. Small corresponding numeric label
- 3. Colored label indicating tube size
- 4. Background bar code label to identify empty tube positions

Replacement labels are available to replace damaged ones.

- Place the large label so it is centered between the raised markings on the front. The bottom of the label must be even with the lower edge of the sector base (Figure 2-2). Smooth out any wrinkles or air bubbles which may appear.
- 2. Place the small numeric label square to the smooth marking on the top of the sector (Figure 2-2). This allows for easy identification of the sector while on the sample wheel.
- 3. Verify that each sector is being identified correctly by performing the Sector Reader Test (See Diagnostics and Troubleshooting Guide, Paragraph 3.5.4.3).

NOTE

If a label must be replaced, remove the old label prior to applying a new one.



- 1 Sector Bar Code Label
- 2 Small Numeric Label
- 3 Colored Label Indicating Tube Size
- 4 Background Bar Code Label

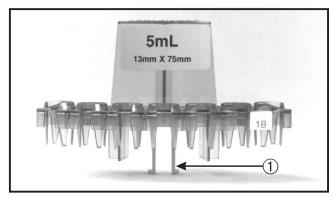
Figure 2-2. CX4CE/CX7 Sector Labels

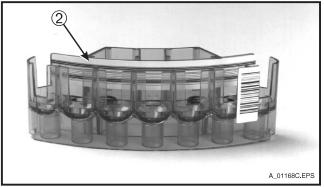
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2.5.3 Replacement of Sector Background Labels

To replace the background label, the sector must be disassembled according to the following steps (refer to Figure 2-3). Note that step one applies to CX7 **DELTA** sectors only.

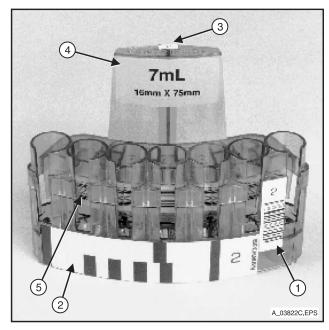
- To prevent the sector bar code label from tearing, use a sharp cutting tool to cut the sector bar code label between the number and the beginning of the bar code symbol. Cut along the line where the top half of the sector separates from the bottom half of the sector.
- 2. Turn the sector upside down and locate the two retaining clips.
- Pinch the retaining clips together and at the same time, pull the two halves of the sector apart.
- 4. Apply the background bar code label so that it rests evenly from left to right, and so that the top edge of the label is flush with the top edge of the sector (bottom half).
- 5. Snap the sector back together.





- 1 Retaining Clips
- 2 Disassembled Sector and Proper Application of Background Label

Figure 2-3. Disassembled Sector for Application of Background Label



- 1 CX4/CX7 DELTA Sector Bar Code Label
- 2 CX4CE/CX7 Sector Bar Code Label
- 3 Small Numeric Label
- 4 Colored Label Indicating Tube Size
- 5 Background Bar Code Label

Figure 2-4. Sector Labels For Both Systems

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2.6 INSTALLATION SPECIFICATIONS

Table 2-1 lists the installation specifications for the SYNCHRON CX4/CX7.

Table 2-1. Installation Specifications

DIMENSIONS (without system console and printer)

Instrument - CX4: H 69 in (175 cm)

D 30 in (77 cm)

L 47 in (119 cm)

Instrument - CX7: H 69 in (175 cm)

D 30 in (77 cm)

L 74 in (188 cm)

System Console Terminal: H 18.8 in (54.8 cm)

D 15.7 in (39.9 cm) L 15.0 in (38.1 cm)

Keyboard: H 1.5 in (3.81 cm)

D 8.25 in (21.0 cm) L 19.25 in (48.9 cm)

SYSTEM WEIGHT (APPROXIMATE)

CX4: 785 lbs (357 kg) CX7: 1135 lbs (516 kg)

SYSTEM POWER REQUIREMENTS

Operating Range: 200 - 240 VAC

220 VAC nominal, approximately

20 amp current rating

Frequency: 50/60 Hz

BTU Generated:

CX4: 4972 BTU/hour CX7: 6400 BTU/hour

Current:

CX4: 6 A nominal CX7: 8 A nominal

70 A peak for 100 msec at power on

Connector: 20 A current rating

Nema L6-20R Twistlock

Printer: Okidata Microline 320 Printer

220 /240 VAC, 50/60 Hz

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Table 2-1. Installation Specifications (Continued)

SYSTEM AMBIENT OPERATING 18°C to 30°C for 37°C operation (for 50 cycle operation use)* **TEMPERATURE RANGES:**

18°C to 30°C for 37°C operation (for 60 cycle operation use)**

18°C to 23°C for 30°C operation

Warm-up Time: 2 hours after installation

30 - 85% noncondensing, at any temperature Relative Humidity:

WATER REQUIREMENTS

Inlet Pressure: 30 psig minimum

90 psig maximum

Flow Rate: 6.5 liters/hour, minimum continuous flow

200 mL/minute, intermittent peak flow

15 - 25°C Temperature:

NCCLS Class II Water Quality:

Filter to 0.2 microns absolute

Specific resistivity: minimum of 1.0 megohm-cm, 25°C

Total Bacteria Count: <10 cfu/ml Dissolved Silicate: <0.1 mg/L

DRAIN REQUIREMENTS***

7.1L/hr. CX7 Delta and a CX7 system maximum 6.9L/hr. CX4 DELTA and a CX4CE system maximum

Drain height: 39" maximum pH of system waste: 5.5-11

1.5" I.D. ABS or PVC drain stand pipe

Drain hose 15 ft. (supplied)

NOTE: Open floor or sink drains may have a tendency to

accumulate excessive foam from waste line. A 1.5" I.D. straight or trap drain stand pipe is the recommended drain configuration in

accordance with local plumbing codes.

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Instruments shipped prior to February 1992 have an ambient operating temperature range of 18°C to 26°C unless retrofitted with Thermal Upgrade (P/N 756957).

^{**} Instruments shipped prior to February 1992 have an ambient operating temperature range of 18°C to 28°C unless retrofitted with Thermal Upgrade (P/N 756957).

^{***} If a Continental Water Modulab™ water system is used, provision must be made for its "throwaway" water requirement of approximately 100 liters per hour.

Section 3 SYSTEM DESCRIPTION

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Section 3 SYSTEM DESCRIPTION

This section provides information on the various functions and features of the SYNCHRON CX4/CX7 Systems. It is designed to familiarize the user with the location and function of the various components of the system.

3.1 GENERAL DESCRIPTION

CX4 DELTA, CX4CE

The SYNCHRON CX4 DELTA (Figure 3-1) and the SYNCHRON CX4CE (Figure 3-2) Systems are microprocessor-controlled random access chemistry analyzers. The systems are designed to perform endpoint, rate, nonlinear quantitative assays, and qualitative drugs of abuse assays.

The main analytical unit can house a maximum of 24 chemistries in the reagent storage area. Reagents are contained in a three-compartment plastic cartridge. Each cartridge contains a bar code label that is automatically scanned during a reagent load procedure. (For details, refer to Paragraph 6.2, Reagent Load.)

The information contained on the cartridge bar code label provides for automatic chemistry identification, reagent location assignment, and the basis for the reagent inventory management system. In addition to Beckman Chemistry Reagents, 100 user-defined methods can be entered and stored in the instrument for analysis. (Refer to Section 8.0, User-Defined Chemistries.)



- 1 -CX4 DELTA
- 2 -CX3 DELTA (CX7 DELTA Users Only)

Figure 3-1. SYNCHRON CX4/CX7 DELTA System

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1 - CX4CE

2 - CX3 (CX7 Users Only)

Figure 3-2. SYNCHRON CX4CE/CX7 Systems

Samples are inserted into individual sectors, with each sector capable of holding 7 samples. Samples may be placed in sample cups or primary sample tubes. The sectors are placed on an autoloader, a mechanism which, under microprocessor control, automatically transfers each sector onto the sample turntable at the appropriate time for processing. Aspiration and dispensing of sample and reagent are controlled through the use of direct-drive positive-displacement syringes.

Sample and reagents are added and mixed every 16 seconds into one of 80 glass cuvettes situated on the reaction carousel. During one half of the 16-second cycle, the reaction carousel is rotated at a speed of 90 rpm (approximately 10 rotations) during which the cuvettes pass through the optics station and the absorbances are read.

Operator interaction with the instrument is primarily through the adjacent system console, which consists of a personal computer (PC), CRT monitor, a keyboard, and 80-column printer. The system console provides the communication between the operator and the computer system.

Routine operation will typically involve programming samples, loading reagents, or performing any of the special function options that are available. Clear and concise prompts are displayed at appropriate times which provide information to assist the operator in system operation.

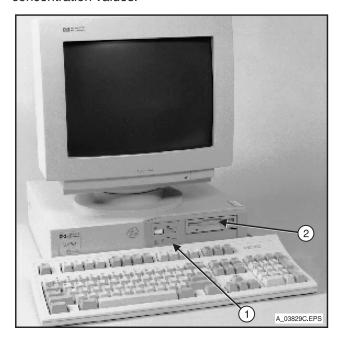
For diagnosis and troubleshooting of the various system components, fault isolation to specific functional areas is accomplished through the use of extensive built-in diagnostics. In the event of an error condition or system malfunction, the operator is immediately informed on the CRT. (Refer to Diagnostics and Troubleshooting Guide, P/N 015-248547.)

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CX3 (CX7 Users Only)

The CX3 provides for the measurement of sodium, potassium, chloride, carbon dioxide (CO₂), glucose, urea nitrogen (BUN), creatinine, calcium (ISE or cup) and total protein in various body fluids. The sodium, potassium, chloride, and calcium electrodes are ionselective devices housed in a flow cell, where a discrete sample analysis is made during each measurement cycle. The CO2 measurement and reference electrodes, both of which are modified pH electrodes, are housed in the upper portion of the same flow cell. Urea Nitrogen (BUN) and glucose are measured in individual chemistry reaction cups by means of a conductivity electrode and polarographic electrode, respectively. Creatinine, calcium (cup) and total protein are measured in individual chemistry reaction cups by means of individual colorimetric electrodes. (For details, refer to Paragraph 4.5, CX3 Principles of Measurement.)

The concentration signals originating at the electrodes in the flow cell and the sensors in the reaction cups are converted by analog amplifiers. Output from the amplifiers is presented to the proper micro-processor, where the signals are scaled and converted to actual concentration values.



- 1 Hard-Disk Drive
- 2 Floppy-Disk Drive

Figure 3-3. Hard and Floppy Disk Drives

3.2 SYSTEM CONSOLE MODULE DESCRIPTION

The SYNCHRON CX System console module consists of four major components: a personal computer (contains hard disk), a CRT display, a keyboard, and a dot-matrix printer. Each unit has configuration flexibility to meet virtually every application need.

3.2.1 PC Console

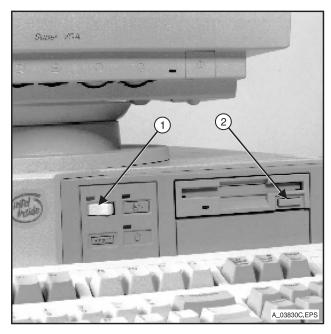
The SYNCHRON CX4 and CX7 Systems are equipped with a personal computer (PC) with a hard drive and a floppy drive. Resident on the hard drive is the main operating program, patient and control data, and other pertinent instrument information. The microfloppy disk drive is used primarily to load, transfer and archive supplementary data. The personal computer is prepared to operate at 220 V AC and 50 or 60 Hz.

A single front-panel indicator lamp lights when either disk drive is selected by the computer (Figure 3-3). The floppy-disk drive also has a single eject button which is used to remove a diskette. (Refer to Paragraph 5.1.3, Diskette Handling, for details on diskette loading.)

WARNING

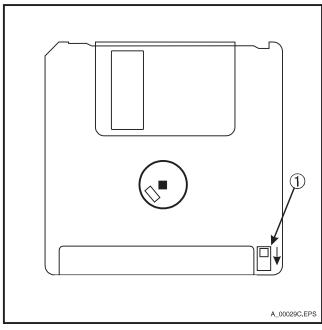
As indicated in Figure 3-4, operators should familiarize themselves with the location of the Computer ON/OFF button and the Diskette Eject button. Pressing the Computer ON/OFF button will corrupt data bases and necessitate database rebuilding.

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- 1 Power ON/OFF Button
- 2 Diskette Eject Button

Figure 3-4. Console Computer



1 - Write Protect Slide Switch

Figure 3-5. 3.5-Inch Micro-Floppy Diskette

3.2.2 Diskettes

The 3.5-inch diskette provides for off-line storage of various supplementary information used by the instrument (Figure 3-5). Each diskette also has a write-protect slide switch that can be enabled (or opened) to prevent data from being written onto the diskette. The slide switch should always be open during normal operations.

3.2.3 Monitor (CRT)

The SYNCHRON CX4 and CX7 Systems uses a 14" color graphics monitor (CRT). The CRT connects to the system console (PC) through a flexible communication cable. The CRT provides the main communication tool between the operator and system functions. During routine operation such as sample programming, reagent loading, or one of the many special functions, the available options and operational instructions are presented clearly on the CRT.

The monitor is equipped to operate at 220 V AC and 50 Hz or 60 Hz. The monitor sits on a swivel base, which allows for 360-degree movement and also provides for adjustment of the tilt for operator comfort.

3.2.3.1 Contrast and Brightness

The control dials for contrast and brightness of the display are both located on the lower front of the monitor (Figure 3-6). The contrast control dial adjusts the contrast of all intensities. The brightness control adjusts the brightness of the display.

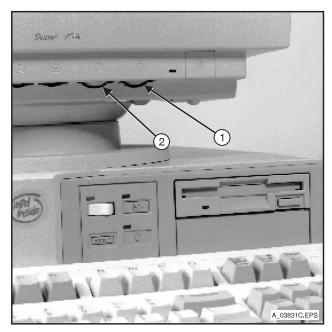
To adjust the brightness:

- 1. Turn the contrast control to the right as far as it will go.
- 2. Turn the brightness control to the right until the background lines on the screen are clearly visible.
- 3. Adjust the contrast control to the left to give a pleasing level of display.
- 4. Turn the brightness control to the left until the background lines just disappear.

NOTE

The location of the Brightness and Contrast Control dials may vary depending on the model of personal computer monitor. The symbols for these control dials and adjustment instructions are the same as described in Paragraph 3.2.3.1, regardless of model.

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- 1 Brightness Control Dial
- 2 Contrast Control Dial

Figure 3-6. Adjusting Display Brightness

3.2.4 Keyboard

The keyboard (Figure 3-7) consists of a standard type-writer layout with the addition of several specialized keys. The keyboard connects to the system console by way of a coiled extension cord. All instructions for programming the instrument, as well as the entry of pertinent data, are accomplished through this keyboard.



Figure 3-7. Keyboard

The keys on the keyboard are divided into four groups to maximize operational efficiency. These include:

Special Operation Keys Function Keys Cursor Movement Keys Alpha-numeric Keys

Only the keys which are applicable to the particular screen being displayed are functional. Pressing a nonfunctional key triggers a beep and displays the message "invalid key." The next valid key pressed erases the message.

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The following is a brief description of the keys:

Special Operation Keys

MASTER SCREEN



Returns the operator to the **MASTER** Screen from any other screen or level in the interface (there are exceptions in the Diagnostics Mode). Also locks in any programmed instruction into the computer.

PREV SCREEN



Returns the operator to the last screen or next higher level from the screen currently displayed, including the closing of windows. This key will also lock in any programmed instruction into the computer. Repeated use will eventually bring the operator to the **MASTER** Screen.

ALARM STATUS



Terminates audible alarm in the event of a system error. Error window will remain displayed until the **PREV SCREEN** key is pressed.

SELECT



Allows the operator to choose desired options from any menu by marking or highlighting in reverse video. Pressing this key again at the same field will deselect the option.

PAGE UP / PAGE DOWN



Scrolls through pages of information which does not fit the dialogue area of one screen. When there is more information to display than is on the current screen, the prompt (more...) appears in the message box.

Figure 3-8. Keyboard - Master Screen, Prev Screen, Alarm Status, Select, Page Up, and Page Down Keys

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START



Homes the system and then begins the chemistry analyses on the instrument. It is effective only from the **MASTER** or **CAROUSEL STATUS** Screen.

PAUSE



Signals the system to stop scheduling tests and dispensing reagent for new tests after current sample is complete. ISE and CX4 may be paused independently. The ISE and CX4 then goes to a standby condition. All cuvettes having reagent or sample dispensed prior to pressing **PAUSE** will run to completion before going to **STANDBY**.

SYS HOME



Returns all mechanical assemblies to their home positions.

SYS IDLE



Initiates power-down of specific mechanical and electronic assemblies. To be used if system is not used for a prolonged period of time. Also, prior to reset or power-down it is recommended that idle be used. Effective only when the system is in **STANDBY** or **STOPPED**.

Figure 3-9. Keyboard - Start, Pause, Home and System Idle Keys

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ENTER

Enter

Locks a command programming instruction into the computer. Also advances the cursor to the next input field.

PRINT SCREEN

Print Screen Provides a printed copy of the current screen display.

CLEAR



Erases input at current edit field. Also used to clear selections in a window, and to clear sample programming from a cup.

EMERG STOP



System immediately becomes inactive. Using the **EMERG STOP** key results in loss of all sample or reagent already dispensed into the cuvettes, and suspends ISE autopriming until system is returned to standby by pressing **SYS HOME**.

CAUTION

Emergency stop is to be used for potentially hazardous situations only unless otherwise specified within a system procedure.

Figure 3-10. Keyboard - Enter, Print Screen, Clear, and Emerg Stop Keys

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Function Keys

F1 - F8

Multi-function keys correspond to defined functions displayed at the bottom of each screen. Prompts will instruct the operator to select the appropriate function

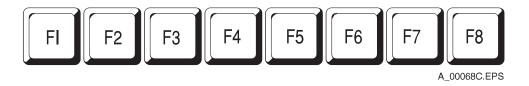


Figure 3-11. Keyboard - Function Keys

Cursor Movement Keys

Four Cursor Directional Arrows ($\leftarrow \uparrow \downarrow \rightarrow$)

Allow the operator to quickly move the cursor in any direction to the next active field within a screen or window. The cursor will wrap around when the limits of the screen have been exceeded

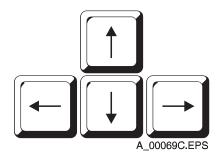
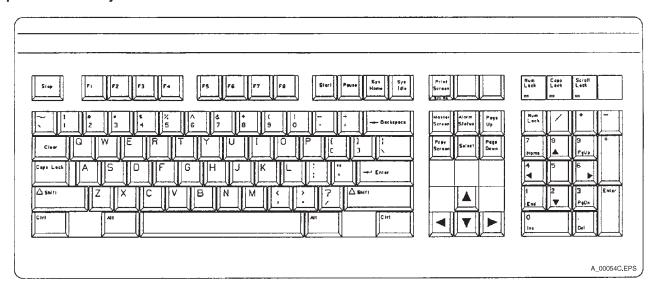


Figure 3-12. Keyboard - Cursor Directional Arrow Keys

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Alpha-Numeric Keys



Numeric keys	Used for entering numeric selections: Sector numbers, ID numbers, normal ranges, etc.
- (dash)	Used to program an inclusive group of numbers. For example, 1 through 8 is entered 1-8.
, (comma)	Used to program multiple cups and sectors which are not in sequential order. For example, 1,5,7,9.
. (period)	Used as a decimal.
Alpha keys	Used for entering alphabet characters: Patient name, control name, comments, sample ID, etc.
SHIFT	Causes the upper case characters of a key to be produced when pressed.
CAPS LOCK	Causes the 26 alphabet characters to stay in shift (uppercase) when it is depressed. The Caps Lock key must be pressed again to release.
BACK SPACE	Moves the cursor one space to the left each time the key is pressed. Each character backspaced is cleared.
SPACE BAR	Advances cursor one space to the right each time bar is typed. Any character under the cursor is replaced by a space.

Figure 3-13. Keyboard - Alpha and Numeric Keys

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An Okidata Microline 320 dot-matrix printer is used for hard-copy printouts (Figure 3-14). Refer to Table 2-1 for printer power specifications. The printer connects to the PC by way of a cable. In addition to providing a permanent record of patient results, printouts of other instrument data such as calibration information, reagent status, and system parameters can be obtained. The printer outputs at a rate of up to 160 characters per second. The controls and indicators on the front panel (Table 3-1) are used to set up the printer for output. (Refer to Paragraph 5.1.2, Printer Setup, for further instructions.)

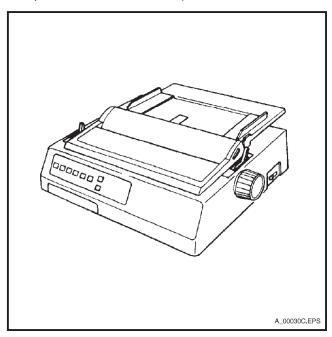


Figure 3-14. 80-Column Printer

PRINT QUALITY AND CHARACTER PITCH

Two important features of the Okidata Microline 320 are the ability to select Print Quality and Character Pitch. These selections are located on the right side of the front panel control (Figure 3-15).

There are three types of print quality available: Near Letter Quality (NLQ), which is the highest level of print quality; Utility (UTL), a higher speed printing for high volume data printing; and High Speed Draft (HSD), which is the highest speed of printing available.

Character Pitch determines the width of the characters, indicated in characters per inch (cpi). PROP (proportionally spaced) is not available in High Speed Draft. Printer must be set to Epson FXe emulation for new report features to operate properly. Printer must be set to character set II for local languages to operate properly. The operator must set the character pitch

with the reports setup feature. See Section 6 paragraph 6.5.1.5 Reports Setup.

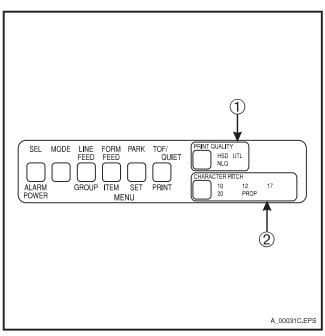
For other features of the Okidata Microline 320 refer to the printer manual that came with your system.

Table 3-1. Printer, Front Panel

The following is a brief description of the printer frontpanel lights:

POWER Light	When lit, indicates printer power is on.
ALARM Light	When lit, indicates printer is out of paper. (Also lights when printer fails memory self-test or when error condition exists, i.e. printer jam).
SELECT Light	When lit, indicates printer is ready to print data. Printer is off-line when light is out.
LINE FEED	Advances paper one line.
FORM FEED	Advances paper to next top-of-form position.
*TOF	Sets top of form, the location on printer paper where printer begins printing.

^{*} Enabled only when SELECT light is out (i.e. printer is off line).



- 1 Print Quality
- 2 Character Pitch

Figure 3-15. Printer Control Panel

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3.3 COMPUTER

The SYNCHRON CX System incorporates four types of microprocessors:

- 2-3 Z8001 microprocessors: one located on the Master Analog Controller (MAC) Board, one located on the CX4 Central Processing Unit (CPU) Board, and one located on the CX3 (CX7 only) CPU Board.
- 2 NSC-800 microprocessors: one located on the CX4 Master Motion Controller (MMC) Board and one located on the CX3 MMC Board.
- 12 TMS 7002 or Phillips 8032 microprocessors: located on the Motor System Controller Boards.
- 1 INTEL 80386 or 486 microprocessor: is located on the PC console.

The functions of the microprocessors provide for complete control of system operations such as reagent pipetting and pumping, sample pipetting, cuvette processing, data acquisition, communication with the system console, and calculating and reporting results. It is a multi-tasking system which allows the simultaneous operation of the analyzer and the use of the data console to access other management functions.

3.4 INSTRUMENT MODULE DESCRIPTION

The modular design concept introduced many years ago by Beckman Instruments is maintained in the SYNCHRON CX Systems. This approach to instrument engineering allows for easy access to component areas, thereby minimizing disruption in the routine operation of the system.

The basic modules of the CX4 are the sample handling system, reagent handling system, syringes, cuvette reaction system, hydropneumatics, and electronic circuit boards.

These modules are illustrated and described in succeeding paragraphs.

CX4

3.4.1 CX4 Sample Handling Modules

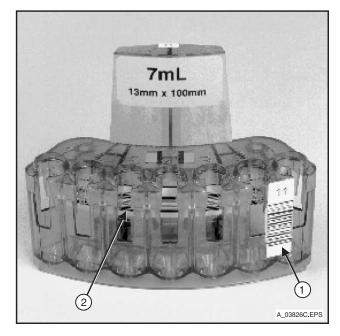
The sample handling system consists of the following components:

Sample Sectors
Autoloader Assembly
Sample Carousel Assembly
Sample Probe/mixer Assembly
Sample Probe/mixer Wash Cup Assembly

The sample handling system is used to transport individual sectors, each containing up to seven (7) samples, for processing and analysis. Each component of the sample handling system is described in detail in the paragraphs that follow.

3.4.1.1 Sample Sectors

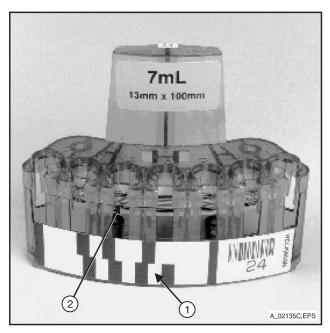
A sample sector is a high density polyethylene semicircular holder designed to house up to seven (7) individual samples. (Figure 3-16). Attached to the front of each sector is an adhesive label that contains an identification number from 1 to 60 and a corresponding bar code symbol. This sector label may be placed vertically (CX4/CX7 DELTA users) as in Figure 3-16 or horizontally (CX4CE/CX7 users) as in Figure 3-17. Figure 3-18 shows a sector which has both vertical and horizontal labels and may be used on both systems. At the top of the sector is a small numeric label (from 1 to 60) which corresponds to the label found on the front of the sector. This small numeric label allows easy viewing and identification of the sector while on the sample carousel. A colored label is located on the upper face of the sector. These labels identify sample tube size for corresponding sectors. Also found on the sector is a background bar code label which allows the instrument to detect empty sample positions.



- 1 Sector Label
- 2 Background Label

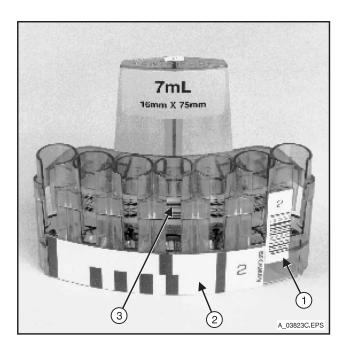
Figure 3-16. Sample Sector (CX4/CX7 DELTA)

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- 1 Sector Label
- 2 Background Label

Figure 3-17. Sample Sector (CX4CE/CX7)



- 1 Sector Label for CX4/CX7 DELTA
- 2 Sector Label for CX4CE/CX7
- 3 Background Label

Figure 3-18. Sector Labels for Both Systems

WARNING

There are two types of sectors. Only amber-colored SYNCHRON sectors labeled 'centrifuge' can be centrifuged. The solid gray/beige sectors will not withstand the force of centrifugation and may be damaged if centrifuged. In addition, instrument alignment is different for these two sectors and they cannot be used together. Refer to Beckman instructions 015-249326-A.

During the process of sample programming, in the sector mode, the operator identifies the respective sector and cup numbers for each patient and control to be analyzed. (Refer to Paragraph 6.4, Sample Programming, for complete instructions.) Individual samples are placed into the sector. All sectors to be processed are then placed onto the autoloader tray.

CAUTION

The 16mm x 75mm and 16mm x 100mm primary sample tube sectors only accept their corresponding tube sizes. The 13mm x 100 mm sectors accept Microtubes in addition to primary sample tubes. The 13mm sectors accept 0.5 and 2.0 mL disposable cups. Sample cups of 0.25 mL are *NOT* recommended because the decreased conical depth of these small cups may cause damage to the probe assembly.

3.4.1.2 Autoloader Assembly

The autoloader assembly is a mechanical device that provides for automatic and continuous loading and unloading of sample sectors to and from the sample carousel. The assembly consists of an autoloader cover, two front panel push-buttons, a sector tray, and a sector transfer wheel.

The autoloader is enclosed in an autoloader cover (Figure 3-19).



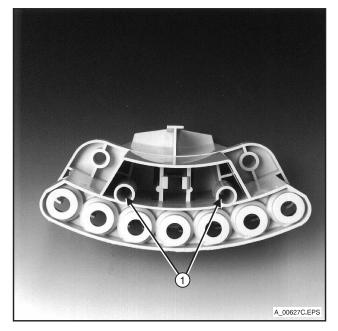
1 - Autoloader Cover

Figure 3-19. Autoloader Cover

Located below the autoloader cover is a fixed-position holding tray that provides for the placement of up to three sample sectors. Sector positions are identified on the tray as LOAD, B, C. The LOAD position represents the sector that is next to be loaded.

Situated in the center of the sector tray is a four-spoke transfer wheel. Each spoke has two positioning tabs which are also used as attachment guides during the loading and unloading of sectors. The transfer wheel is capable of both vertical and rotational movement. A stepper motor provides discrete rotational position movement, while air pressure derived from the hydropneumatic system drives the vertical motion.

At the beginning of the autoload cycle, the transfer wheel is in the down position, with the individual sectors residing in the sector tray positions. Air pressure then drives the wheel upwards. During its upward motion, the positioning tabs attach to the two mounting holes found on the underside of the sector (Figure 3-20) and lifts the sectors off the tray (Figure 3-21).



1 - Sector Mounting Holes

Figure 3-20. Sector Mounting Holes



- 1 Sector Tray
- 2 Transfer Wheel

Figure 3-21. Autoloader Assembly

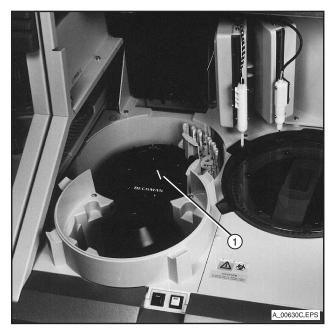
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Similarly, a completed sector ready to be unloaded is lifted off the sample carousel during this cycle. The transfer wheel then rotates clockwise one sector position. The air pressure is then reversed, which causes the wheel to descend to its down position. During this autoload cycle, a new sector has been transferred onto the sample carousel for processing, the sectors residing on the tray have been indexed one position clockwise, and a completed sector (if present) has been unloaded to the tray for removal. (For complete instructions on autoloader operation refer to Paragraph 5.5.)

3.4.1.3 Sample Carousel Assembly

The sample carousel assembly consists of a six-position sample carousel, a reflective sensor reader (CX4CE) or laser bar-code reader (CX4 DELTA) for sectors, a laser bar-code reader for primary sample tubes and a sample turntable cover.

The sample carousel is a discrete position stepper motor-driven rotational device. Six positions are available on which the individual sample sectors can be placed for processing (Figure 3-22). Under normal operation, five positions are used for routine processing and one is reserved for STAT sectors.



1 - Sample Carousel

Figure 3-22. Sample Carousel

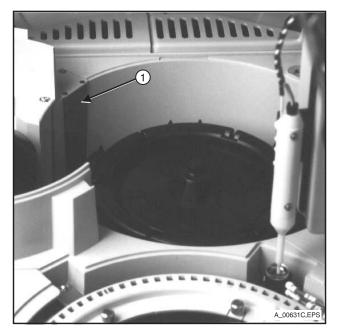
Typically, sector placement and removal are under microprocessor control and are coordinated to operate in conjunction with the autoloader assembly. However, manual placement of sectors onto the carousel can also be achieved while the instrument is in standby.

NOTE

If sectors have been manually placed on the carousel, the operator must press **START** to initialize processing of all sectors.

CX4CE and CX7 Systems

Situated on the outer left perimeter of the turntable assembly is a reflective sensor reader (Figure 3-23). Following the placement of a new sector onto the sample carousel, the turntable rotates in a clockwise direction to allow the optical reader to scan the sector label for identification. The identified sector number and its associated sample program information are used by the chemistry scheduler to optimize the order of testing for STAT processing.



1 - Reflective Sensor Reader

Figure 3-23. Reflective Sensor Reader

Also found on the outer right perimeter of the turntable assembly is a laser bar code reader for scanning sample bar code labels (Figure 3-24). Refer to section 11 for a description of the CAUTION labels for the laser bar code reader.

CX4 DELTA and CX7 DELTA Systems

Situated on the outer right perimeter of the turntable assembly is a laser bar code reader for scanning both sample bar code labels and sector bar code labels. Refer to Section 11 for a description of the CAUTION labels for the laser bar code reader.



1 - Laser Bar Code Scanner

Figure 3-24. Laser Bar Code Scanner

WARNING

Do not tamper with or remove housing of sample bar code reader.

The sample bar code reader is a Class II moving beam laser scanner. When the instrument status on the console displays the message "Running", "Homing" or "Diagnostics" the laser may be on. At all other times, the laser is off.

Once the sector has been scanned, it is rotated in front to the sample bar code scanner. After three consecutive reads that positively identify the sample, the system accepts the sample ID as valid.

As a sector is ready for processing, the turntable rotates into position for sample aspiration. All tests programmed for a given sector are processed according to the chemistry scheduler. Completed sectors will rotate into position for removal by the autoloader transfer wheel at the appropriate time.

A protective cover extends over the sample turntable area (Figure 3-25). The cover may be removed by the operator to manually place or remove sectors from the sample carousel when the instrument is in STANDBY.

NOTE

If the tray cover is removed during sample processing, do not remove sectors that are incomplete and that contain tests to be processed. If they are removed, the instrument will attempt to process all samples which were programmed resulting in lost reagent.



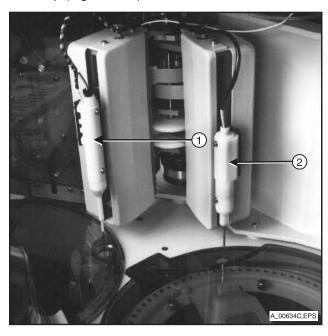
Figure 3-25. Sample Turntable Cover

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3.4.1.4 Sample Probe/Mixer Assembly

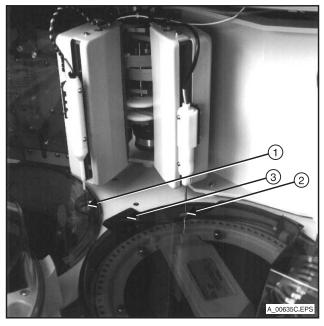
The sample probe/mixer assembly consists of a mechanical structure that supports two moveable cranes (Figure 3-26). Attached to one crane is a pickup probe, while the other crane supports a high-speed gold-plated cylindrical mixer. The probe incorporates a liquid level sensor to detect the sample surface. The level sense circuitry is based on radio frequency (RF) detection and determines the correct probe depth into the sample.

Each crane is capable of both rotational and vertical motion and each is controlled by two independent stepper motors. The sample probe crane can access one position on the sample carousel, one cuvette on the reaction carousel, and the sample probe/mixer wash cup (Figure 3-27).



- 1 Sample Probe Crane
- 2 Sample Mixer Crane

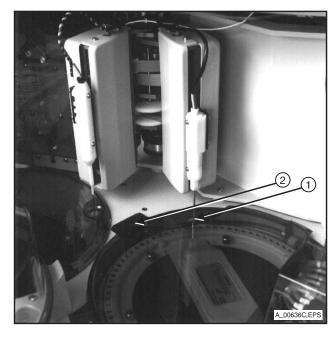
Figure 3-26. CX4 Sample Probe/Mixer Assembly



- 1 Sector Sample Position
- 2 Cuvette for Sample Addition
- 3 Sample Probe/Mixer Wash Cup

Figure 3-27. CX4 Sample Probe Positions

The rotational axis of the second crane allows the sample mixer to access one cuvette on the reaction carousel and the sample probe/mixer wash cup (Figure 3-28).



- 1 Cuvette for Sample Addition
- 2 Sample Probe/Mixer Wash Cup

Figure 3-28. CX4 Sample Mixer Positions

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3.4.1.5 Sample Probe/Mixer Wash Cup Assembly

The CX4 sample probe/mixer wash cup is a two-piece assembly into which either the pickup probe or mixer is lowered (Figure 3-29). Three pressurized jets, which are located in the lower section of the wash cup, emit a diluted stream of wash solution that cleanses the outer surface of the probe/mixer. Five other jets deliver compressed air, which strips the residual water from the probe/mixer before it retracts from the cup. A gravity drain at the bottom of the cup collects the effluent and directs it to the waste receptacle.

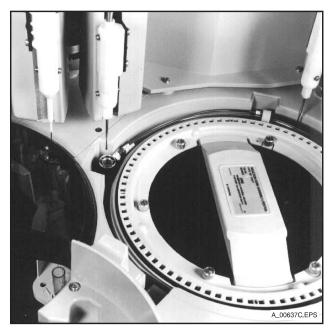


Figure 3-29. CX4 Sample Probe/Mixer Wash Cup

3.4.2 Reagent Handling Modules

The reagent handling system consists of the following components:

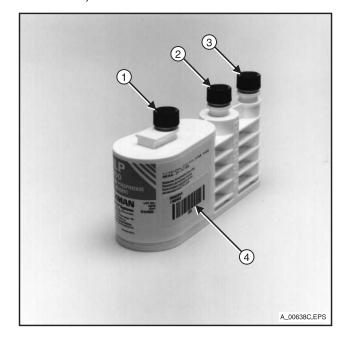
Reagent Cartridges Reagent Carousel Reagent Probe/mixer Assembly Reagent Probe/mixer Wash Cup Assembly

The reagent handling system is used to transfer reagent from the individual cartridges to the reaction cuvettes for processing and analysis of the requested chemistry tests. A detailed description of each component is presented in the following paragraphs.

3.4.2.1 Reagent Cartridges

Reagent cartridges are disposable polypropylene containers that house the individual liquid reagent components necessary to perform a chemistry test. Each wedge-shaped cartridge is designed to fit into the circular reagent carousel storage area. A cartridge consists of three individual compartments designated A, B, and C, respectively. Maximum volumes for the three compartments are: A - 110 mL, B - 18 mL, and C - 4 mL.

A chemistry description and bar code identification label is located on each cartridge (Figure 3-30). The bar code label, which is read as each cartridge is loaded into the reagent compartment, serves to automatically identify to the instrument a chemistry and its data base for this corresponding carousel position. (Refer to Paragraph 6.2, Reagent Load, for complete instructions.)



- 1 Compartment A
- 2 Compartment B
- 3 Compartment C
- 4 Bar Code Label

Figure 3-30. Reagent Cartridge

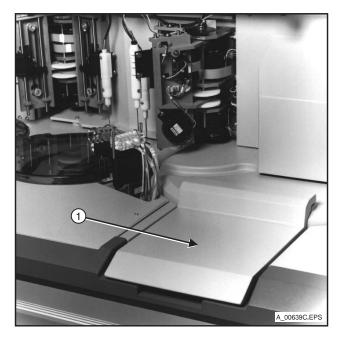
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3.4.2.2 Reagent Carousel

The reagent carousel compartment provides an on-instrument storage area for the individual reagent cartridges. A total of 24 reagent cartridges can be stored at one time. The storage compartment is refrigerated and fan-cooled to maintain a temperature of 5° C ($\pm 3^{\circ}$ C). Mounted to the carousel is a stepper motor-driven rotor. The rotor provides the stepwise rotational movement required to position a selected cartridge for aspiration by the reagent probe.

The operator can load or remove reagent cartridges by lifting the access door situated at the front of the carousel (Figure 3-31A). An interlock switch is incorporated into the door to prevent it from being opened during the rotation of the carousel. Similarly, if the door is open, the switch will inhibit rotation of the carousel while cartridges are being changed.

The reagent bar code reader, (Figure 3-31B) situated near the front of the access door, scans each label during the loading or removal of reagent cartridges. An audible signal is activated to acknowledge successful reading of the label. (Refer to Paragraph 6.2 for complete instructions on loading reagent cartridges.)



Α

1 - Access Door



В

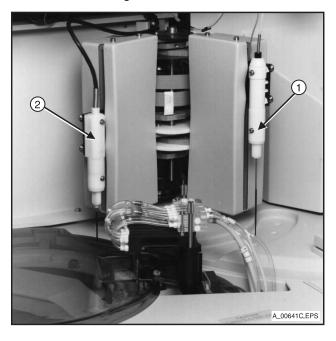
1 - Bar Code Reader

Figure 3-31. Reagent Carousel

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3.4.2.3 Reagent Probe/Mixer Assembly

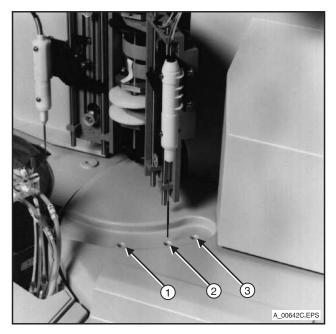
The reagent probe/mixer assembly consists of a mechanical structure that supports two moveable cranes. Attached to one crane is a pickup probe, while the other crane supports a high speed gold-plated cylindrical mixer (Figure 3-32). The probe incorporates a liquid level sensor. Level sensing, which is based on radio frequency (RF) detection, determines the surface level of the reagent.



- 1 Reagent Probe Crane
- 2 Reagent Mixer Crane

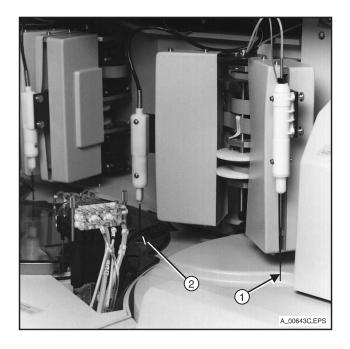
Figure 3-32. Reagent Probe/Mixer Assembly

Each crane is capable of both rotational and vertical movement, and each is controlled by two independent stepper motors. The reagent probe is capable of accessing any of three reagent cartridge compartments (Figure 3-33), one cuvette position on the reaction carousel, and the reagent probe/mixer wash cup. The mixer crane can access one cuvette position on the reaction carousel (Figure 3-34) and the wash cup. (Refer to Paragraph 4.2 for details on reagent handling.)



- 1 Compartment A Access
- 2 Compartment B Access
- 3 Compartment C Access

Figure 3-33. Probe Positioned over Reagent Cartridge



- 1 Reagent Probe
- 2 Reagent Mixer

Figure 3-34. Mixer Positioned over Reaction Cuvette

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3.4.2.4 Reagent Probe/Mixer Wash Cup Assembly

The reagent probe/mixer wash cup is a two-piece assembly (Figure 3-35) into which either the probe or mixer is lowered. Three pressurized jets, which are placed in the lower section, emit a diluted stream of wash solution to cleanse the outer surface of the probe/mixer. Five other jets deliver compressed air to strip the residual water from the probe/mixer before it leaves the wash cup. A gravity drain at the bottom of the cup collects the effluent and directs it to the waste receptacle.

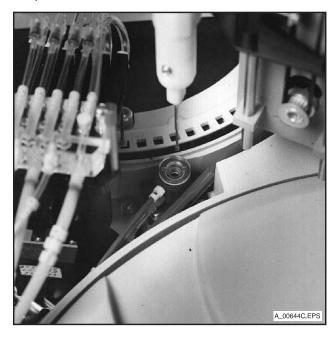


Figure 3-35. Reagent Probe/Mixer Wash Cup

3.4.3 Cuvette Reaction System

The cuvette reaction system consists of the following components:

Reaction Carousel Assembly Photometer Assembly Cuvette Wash Station

The cuvette reaction system is involved in the process of obtaining absorbance readings from each cuvette during the analysis cycle. Following the completion of each chemistry test, the cuvettes are processed through a wash station in preparation for the next chemistry. A detailed description of each component follows.

3.4.3.1 Reaction Carousel Assembly

The reaction carousel assembly (Figure 3-36) supports a total of 80 cuvettes on a radius of approximately 5.5 inches (14 cm). Each cuvette is glass in composition, with a 5 x 5 mm internal cross section, and approximately 30 mm high. The cuvettes are non-disposable and have an indefinite life-span on the instrument. (They remain under warranty for 2 years.)

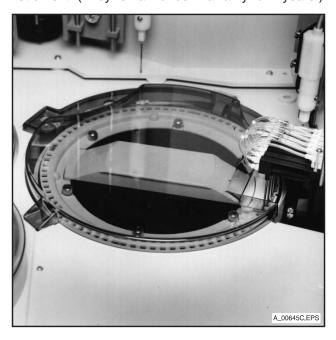


Figure 3-36. Reaction Carousel Assembly

The carousel, which is capable of rotational movement, is controlled by a stepper motor. Every 16 seconds the stepper motor indexes the cuvettes at intervals of 1/80th of a revolution (that is, one cuvette position counterclockwise). During the second half of the 16-second cycle, the carousel spins clockwise at a speed of 90 rpm, during which the cuvettes pass through the optical reading station. The carousel is designed such that the cuvettes are positioned into proper alignment to enable the illumination beam from the photometer unit to pass on a radius directly through the opposing sides of each square cuvette (Figure 3-37). The spin cycle provides for the ability to read absorbances from multiple cuvettes.

The carousel is thermally controlled to either $+30^{\circ}$ C or $+37^{\circ}$ C ($\pm0.1^{\circ}$ C) by a phase change heat pipe. In order to maintain the proper thermal environment, the carousel is enclosed by a trough and a cover.

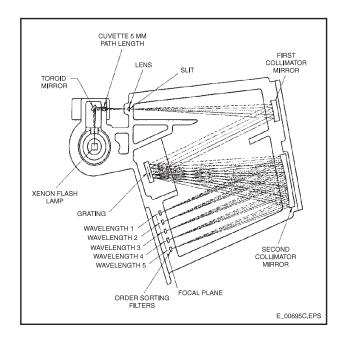


Figure 3-37. Illumination Beam Path through the Cuvette (Photometer Assembly)

3.4.3.2 Photometer Assembly

Attached to the reaction carousel support frame is the photometer assembly. This assembly consists of a xenon pulsed lamp, a discrete 10-position silicondiode detector array, a monochromator housing unit, and associated electronic circuitry (Figure 3-37).

As each cuvette passes through the optics station during a spin cycle, the xenon lamp is flashed and the resultant light beam is transmitted through the opposing sides of the square cuvette. The beam strikes a diffraction grating which then separates the light into a full spectrum. Separate photodetectors are available for the following wavelengths: 340, 380, 410, 470, 520, 560, 600, 650, 670, and 700 nm. The electrical (analog) signal produced when the light strikes the photodetectors is then converted to a numerical (digital) value by the Analog-to-Digital Converter (ADC) Board.

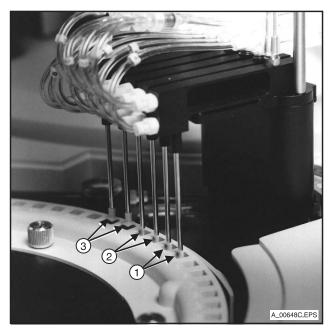
3.4.3.3 Cuvette Wash Station

As viewed from the front of the instrument, the cuvette wash station is located on the right-hand side of the reaction carousel and in front of the reagent probe assembly (Figure 3-38). The wash station consists of six coaxial probes, an elevator assembly, and associated tubing. A stepper motor controls the vertical motion required by the elevator to raise and lower the probes during the washing stage. Compressed air and vacuum from the hydropneumatic assembly provides the ability to aspirate and deliver the appropriate fluids required to complete the wash procedure.



Figure 3-38. Cuvette Wash Station

A complete wash procedure involves three separate stages. To accomplish this in an efficient manner, the six wash probes are divided into pairs, with each pair performing the same function on alternate cuvettes (Figure 3-39). Therefore, a total of six cuvettes can be processed by the wash station simultaneously.



- 1 Probes 1 and 2
- 2 Probes 3 and 4
- 3 Probes 5 and 6

Figure 3-39. Wash Probes

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The function of each probe (from left to right) can be identified as follows:

Probes 1 and 2 serve to aspirate the reaction products (sample and reagent) from each cuvette and transfer them to the waste system. Following the aspiration, wash solution is dispensed into the cuvettes for cleaning.

Probes 3 and 4 are used to aspirate the wash solution dispensed from the previous cycle. This is followed by dispensing deionized water. The deionized water serves two purposes: 1) to rinse wash solution from each cuvette and, 2) to perform a cuvette absorbance check to determine the effectiveness of the cleaning step.

Probes 5 and 6 are equipped with a special square wiper-nozzle tip whose dimensions fit the inner diameter of the cuvette. These probes serve to remove the deionized water and any residual fluid adhering to the inner walls.

NOTE

To maintain the thermal equilibrium of the reaction cuvettes, the wash solution and deionized water are thermally controlled at 27° C to 37° C (if the reaction carousel is set to 37° C), or 26° C to 30° C (if the reaction carousel is set to 30° C).

During routine operation, the cuvette wash procedure is coordinated by the microprocessor to occur at the completion of alternate spin cycles (that is, every 30 seconds). Therefore, three pairs of cuvettes rotate through the different wash stages every other spin cycle. Upon completion of all three stages, the cuvettes have been washed, rinsed, optically verified, dried, and readied for the next chemistry.

3.4.4 Hydropneumatic System

The hydropneumatic system, which is housed beneath the autoloader and sample wheel, consists of the following assemblies:

> Pneumatic/vacuum assembly Hydro assembly Drain assembly

The function of the hydropneumatic system is to provide a continuous source of vacuum, compressed air, cuvette wash, deionized water, and probe rinse solution required by the different functional areas of the instrument. The entire system is mounted on a slideout drawer that allows for easy access by the operator (Figure 3-40). When fully extended, the drawer locks open. To close, push in on the metal tabs, located on each side of the bottom runner of the hydropneumatic unit, move fingers out of the way, and push the drawer in (Figure 3-41). A detailed description of each major assembly is presented in the following paragraphs.

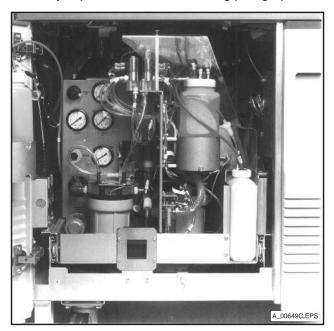


Figure 3-40. Hydropneumatic System

3.4.4.1 Pneumatic/Vacuum Assembly

The major components of the pneumatic/vacuum assembly include the air intake filter, compressor/vacuum pump, pressure tanks, regulator/relief valves, various solenoid valves, and associated tubing (Figure 3-41).

The compressor pump is dual-function: one half provides a pressure source, the other half a source of vacuum. Intake air passes through a filter device and is then pumped by the compressor to an air reservoir tank. A similar tank is used to store the residual vacuum.

CAUTION

The pressure head of the compressor is hot; DO NOT touch.

Flexible polyurethane tubing is used to connect the air and vacuum supply lines to the various assemblies. Each tube is color-coded for easy identification. The colors correspond to the specific functions as follows:

Б .					~-	
Red	high	pressure	aır	supply,	25	psi

(Figure 3-68)

Blue medium pressure air supply, 10

psi (Figure 3-69)

Green low pressure air supply, 5 psi

(Figure 3-70)

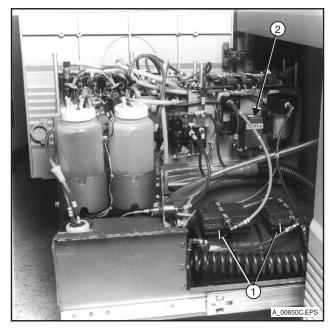
Yellow drain of liquid waste products,

vacuum and exhaust (Figure

3-71)

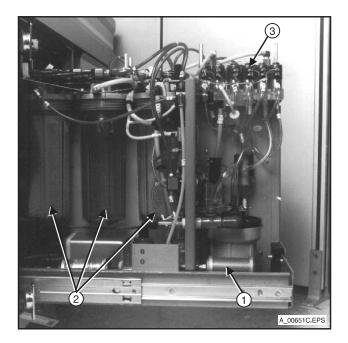
Clear flow of liquid supply (Figure 3-72)

Solenoid valves are used to control the supply of air and vacuum.



Α

- 1 Compressor/Vacuum Pump
- 2 Autoloader Solenoid Valve Button



В

- 1 Air Intake Filter
- 2 Pressure Tanks

3 - Solenoid Valves

Figure 3-41. Pneumatic/Vacuum Assembly Components

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Maximum air pressure is maintained at 25 psi by a relief valve. This source of air is used to:

- 1. Provide a source of forced air required to dry the outside of the sample and reagent probes and mixers in the wash station.
- 2. Open the valve at the bottom of the bubblegenerator assembly.

An air-pressure regulator provides a source of 10 psi air, which is used to:

- 1. Pressurize the reagent probe rinse solution bottle.
- 2. Provide a source of air for the addition of bubbles to the reagent probe rinse solution stream.
- 3. Provide 10 psi air pressure to the deionized water pressure reservoir.
- 4. Pressurize the diluted wash bottles.

A regulator sets the air pressure to 25 psi. This source of air is used by the autoloader transfer wheel to load and unload sectors onto the sample wheel.

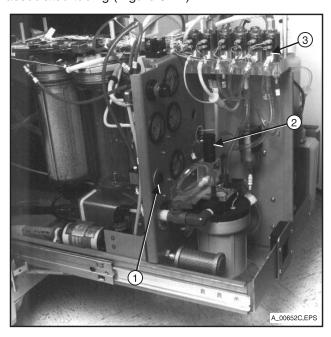
Another regulator sets the air pressure to 5 psi. This reduced pressure is used to:

 Pressurize the wash concentrate bottle, facilitating the delivery and mixing of the concentrate with distilled water.

The vacuum side of the system is primarily used to evacuate reaction products, wash solution, or rinse water from each cuvette as it passes through the cuvette wash station. Vacuum is maintained at a nominal state of 25-30 in-Hg. The effluent is then directed to a waste receptacle, from which waste is periodically emptied to an outside drain.

3.4.4.2 Hydro Assembly

The hydro assembly consists of a pressurized DI water reservoir, master solenoid valve, two float switches, pressure regulator, pressure switch, resistivity sensor, inlet filter unit, various solenoid valves, and associated tubing (Figure 3-42).

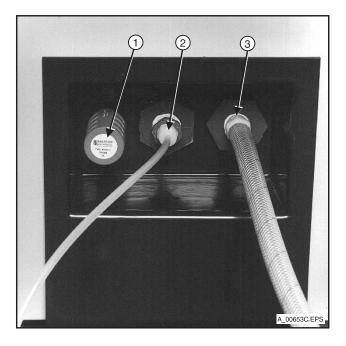


- 1 DI Water Pressure Regulator
- 2 Resistivity Sensor
- 3 Solenoid Valves

Figure 3-42. Hydro Assembly Components

Deionized water is supplied to the instrument from an external source that is attached to an inlet tube connector at the back of the instrument (Figure 3-43A).

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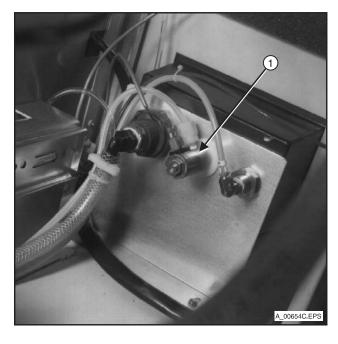


The water supply is controlled by a master shut-off solenoid valve located just behind the inlet connector (Figure 3-43B). The water passes through a filter device and into the pressurized DI water reservoir at the front of the hydro module. Pressure regulation is provided by the 10 psi air supply which is connected to the DI water pressure reservoir. The water pressure reservoir is monitored by a low water supply float sensor which is indicated on the status monitor screen (refer to Paragraph 6.1) and a fill sensor which automatically activates the master solenoid valve.

The deionized water can be manually shut off at the instrument using the shut-off valve (Figure 3-44A & B).

Α

- 1 Vacuum Exhaust Filter
- 2 DI Water Inlet Line
- 3 Drain Line

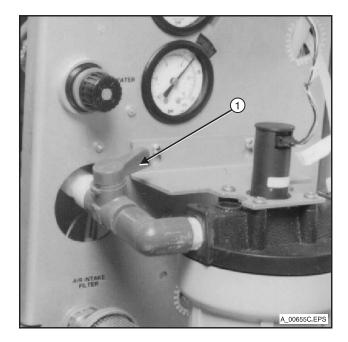


В

1 - DI Water Master Solenoid Valve

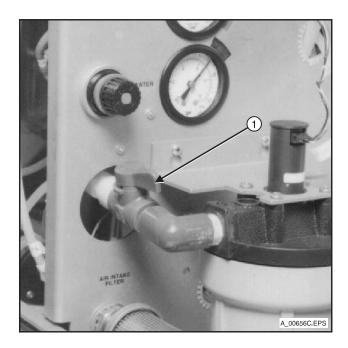
Figure 3-43. Deionized Water Inlet Connection

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Α

1 - OFF Position



В

1 - ON Position

Figure 3-44. Shut-off Valve

CAUTION

Whenever removing the DI (deionized) water supply line, in addition to turning off the instrument shut-off valve, the external instrument supply line should also be turned off.

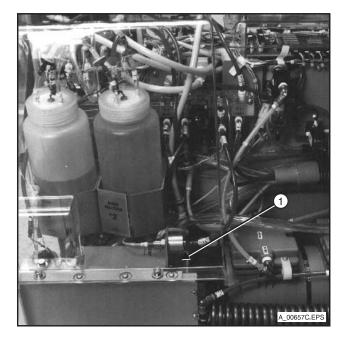
The water supply is also checked for suitable resistivity (minimum 1 megohm-cm) through an in-line conductivity sensor. (For complete details on water requirements, refer to Section Two, Table 2-1.)

Similar to the air/vacuum supply, the water is directed to the different areas of the instrument through individual flexible tubing. Discrete solenoid valves are used to control the water supplied to the respective areas. The water supplied provides the following functions: (1) washing and rinsing of cuvettes in the wash station, (2) internal cleaning of the sample probe, and (3) dilution of the concentrated wash solution.

3.4.4.3 Drain Assembly

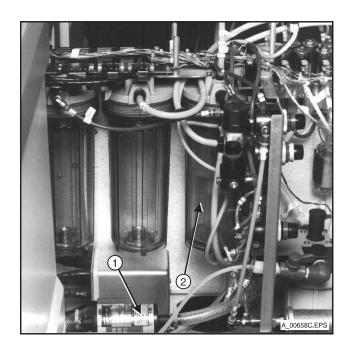
The drain assembly handles all the normal effluent from the various assemblies of the instrument. The major components include liquid trap reservoir, waste receptacle, and drain pump (Figure 3-45).

During the wash cycles, the contents of each cuvette is diverted to the liquid trap reservoir. The effluent is then pumped to the waste receptacle located in the front portion of the assembly. At periodic intervals, the drain pump removes the contents of the waste receptacle through the outlet port of the instrument to a suitable floor or sink drain.



Α

1 - Waste Receptacle



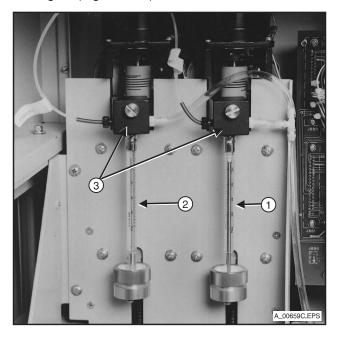
В

- 1 Drain Pump
- 2 Liquid Trap Reservoir

Figure 3-45. Drain Assembly Components

3.4.5 Syringe System

The syringe system provides for the aspiration and dispensing of sample and reagent during the routine operation of the instrument. Two separate syringe assemblies are employed for aspirating and dispensing, a 50 μ L syringe for sample, and a 500- μ L syringe for reagent (Figure 3-46).



- 1 Reagent Syringe
- 2 Sample Syringe
- 3 3-Position Valve Block

Figure 3-46. Syringe System

A stepper motor controls the vertical syringe motion that provides the positive displacement required for the aspirating and dispensing action. Each motor step corresponds to a precise volume. Under microprocessor control, the syringe motor is driven the necessary steps to aspirate or dispense the required volume.

Also associated with the assembly is a three-position valve block that is situated on the top of each syringe. Following sample or reagent dispensing, the valve opens a pathway that permits DI water from the hydropneumatic system to be delivered through the interior diameter of the probes as they are situated in the wash cup.

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3.4.6 Power System

The instrument requires power from a 220 V AC, 50/60 Hz single-phase, 20-amp source. This source, which is the only power required by the instrument, is used directly or indirectly by the respective components through the use of solid-state relay switches, regulators and DC output power supplies.

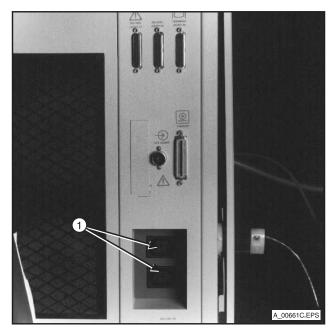
Power is connected to the instrument through the intermediate three-wire power cord with special twist-lock connectors. One end of the connector plugs directly into the back panel receptacle of the instrument while the other end plugs into the appropriate laboratory outlet (Figure 3-47).



Figure 3-47. Power Connector

CX4 Power

In addition to the three-prong receptacle, there are two accessory outlets located on the lower right panel. One is used to connect the UPS (Uninterrupted Power Supply) into which the system console accessory devices (that is, printer, personal computer, and monitor) are plugged in. (See Figure 3-48.)



1 - 220 V Auxiliary Outlets

Figure 3-48. Accessory Outlets

All power is passed through the line conditioner device located in the lower right compartment of the instrument (Figure 3-49). The line conditioner serves to limit the effect of line voltage transients that could damage the sensitive electronic components of the system.

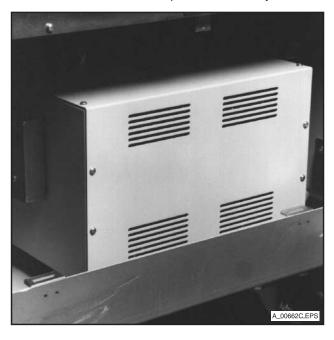


Figure 3-49. Line Conditioner

Two separate circuit breaker/power ON/OFF switches are located on the lower right front panel of the instrument (Figure 3-50). When viewed from the front, the right switch is the MAIN circuit breaker, which controls all power to the instrument. Power to the UPS (Uninterrupted Power Supply) may be controlled independently by the AUX switch located to the left of the main circuit breaker.

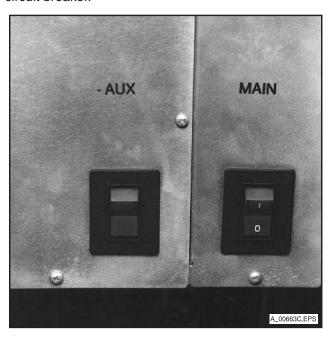


Figure 3-50. Circuit Breaker

CX3 Power (CX7 Users Only)

The CX3 relies on the CX4 for power. The main power line of the CX3 is internally connected to the CX4. The only power switch is an ON/OFF switch which is located inside the lower compartment on the right side (Figure 3-51).



Figure 3-51. CX3 ON/OFF Switch

CX3 Instrument Module Description (CX7 Users Only)

The CX3 consists of the sample probe/crane assembly, ratio pump, CAM multi-pinch valve assemblies, flow mixers, damper assemblies, peristaltic pump assemblies, Solenoid Valves, Electrolyte Injection Cup (EIC), Flow Cell Assembly, Reagent Compartment and Chemistry Reaction Modules. A detailed description of each assembly follows:

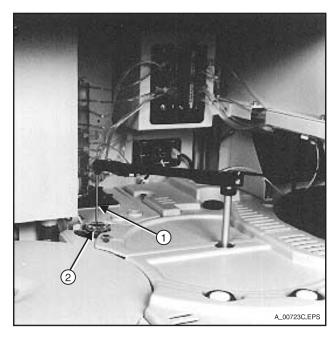
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3.4.7 CX3 Sample Probe/Crane Assembly

The sample probe/crane assembly is a mechanical structure that supports a moveable crane (Figure 3-52). Attached to the crane is a single stainless steel pickup probe.

The crane is controlled by two stepper motors, one for rotational and one for vertical movement. The rotational axis of the crane allows the probe to access the electrolyte injection cup and the samples. The vertical movement allows the probe to move up and down at each rotational position.

Incorporated into the probe design is a liquid conductivity level sensor that is used to detect the sample surface. If the sample probe does not detect sample, the results for that sample are suppressed and the printer prints "NO SAMPLE DETECTED". Sample detection is accomplished by passing a low voltage AC signal between the collar of the sample probe and the probe itself. If the current path is not completed, a "NO SAMPLE DETECTED" condition is detected.



- 1 Sample Probe
- 2 Electrolyte Injection Cup

Figure 3-52. Sample Probe Assembly and Electrolyte Injection Cup

3.4.8 Ratio Pump Assembly

The ratio pump is a stepper-motor driven, multicylinder, positive-displacement pump. It consists of a five-diameter piston housed in five stacked, independent cylinders (Figure 3-53). Each cylinder has one intake line and one output line. The ratio pump cylinders are discussed here as they functionally operate, rather than in numerical order.

The top section, or cylinder one, of the ratio pump has three functions: (1) It contains Electrolyte Reference solution which is delivered to the sample probe; (2) It provides positive displacement for the aspiration of calibrators and samples; (3) It provides pumping action to accurately dispense Electrolyte Reference solution, samples, and calibrators to the EIC (and hence the flow cell) and to the chemistry reaction cups.

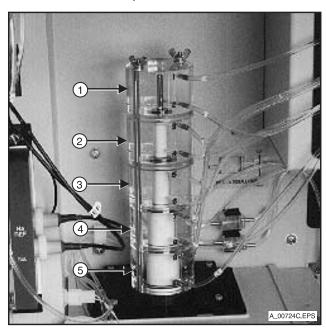
Cylinder two delivers concentrated ISE Electrolyte Buffer to a flow mixer; cylinder five delivers Wash Solution to the same flow mixer. In that flow mixer, the ISE Electrolyte Buffer and Wash Solution are combined in a ratio of 1:5. After thorough mixing, the diluted ISE Electrolyte Buffer is delivered to the EIC where it is used to dilute calibrator, sample, or ISE Electrolyte Reference solution. These are combined in the ratio of 1 part sample to 20 parts diluted ISE Electrolyte Buffer.

Cylinder three delivers concentrated CO_2 Acid Reagent to a second flow mixer; cylinder four delivers wash solution to the same flow mixer. There, these two reagents are combined in the ratio of 1:5. After thorough mixing, the diluted CO_2 Acid Reagent is delivered to the top portion of the flow cell, where it is added to a flowing sample stream in the ratio of 1.3 parts diluted sample to 1 part diluted CO_2 Acid Reagent.

3.4.9 Cam Multipinch Valve Assembly

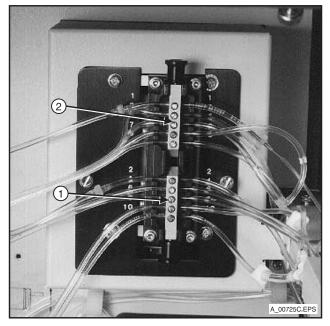
Two valve assemblies provide for fluid flow control to the various portions of the CX3. The assemblies each consist of ten finger-like cam projections. Under microprocessor control, these cam projections release or compress the various reagent flow lines against a pressure bar. This action, in combination with the pressure supplied by the ratio pump, and peristaltic pumps provides for coordinated movement of reagent and sample. The valve camshaft is stepper-motor driven.

Pinch valve "E" (Figure 3-54) handles the electrolyte portion of the system. The second valve, pinch valve "C" (Figure 3-55) controls sipping and draining sequences for the chemistry reaction cups - BUN, glucose, calcium or total protein and creatinine.



- 1 Sample or ISE Electrolyte Reference
- 2 ISE Electrolyte Buffer
- 3 CO₂ Acid
- 4 Wash Solution for CO₂ Acid
- 5 Wash Solution for ISE Electrolyte Buffer

Figure 3-53. Ratio Pump Assembly



- 1 Controls Inlet Tube Lines
- 2 Controls Outlet Tube Lines

Figure 3-54. "E" Pinch Valve Assembly

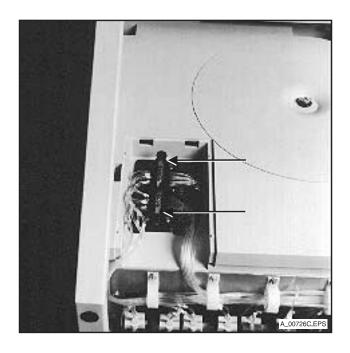


Figure 3-55. "C" Pinch Valve Assembly

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The function of the valve positions can be identified as follows:

"E" Cam Multipinch Valve

/alve Number	Valve Function				
1	Electrolyte Reference Out				
2	Electrolyte Reference In				
3	Electrolyte Buffer Out				
4	Electrolyte Buffer In				
5	CO ₂ Acid Out				
6	CO ₂ Acid In				
7	Wash Solution Out (to dilute CO ₂ acid)				
8	Wash Solution In (to dilute CO ₂ acid)				
9	Wash Solution Out (to dilute electrolyte buffer)				
10	Wash Solution In (to dilute electrolyte buffer)				

"C" Cam Multipinch Valve

Valve Function

Calcium or total protein drain

Calcium or total protein sip

Valve Number

16

17

18

168

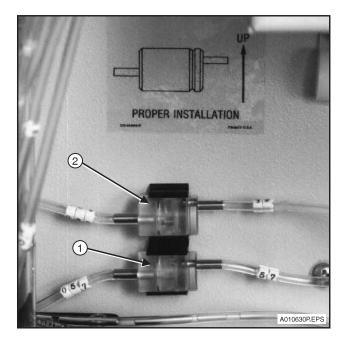
124 Air line 11 Glucose drain 12 Glucose sip 13 Creatinine drain 14 Creatinine sip 15 BUN drain

BUN sip

Air line

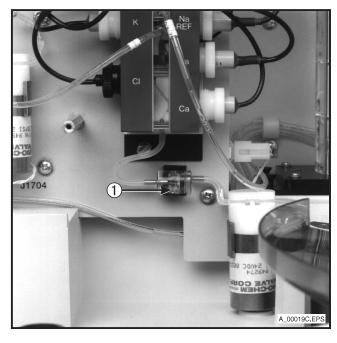
3.4.10 Flow Mixers

CO₂ Acid Reagent and ISE Electrolyte Buffer are each combined independently with wash solution. Two flow mixers help facilitate mixing of these combined reagents (Figure 3-56A & B). After mixing, the diluted CO₂ Acid Reagent is carried to the flow cell, while the diluted electrolyte buffer is carried to the electrolyte injection cup. A third mixer (only on CX DELTA systems) helps facilitate mixing of either sample or ISE Electrolyte Reference with diluted ISE Electrolyte Buffer as it is carried from the EIC to the flowcell for analysis. Each flow mixer must be situated such that the off-centered port, which connects to the input line, is orientated on the top relative to the centered port, which connects to the output line (Figure 3-57).





- 1 CO₂ Acid/Wash Solution
- 2 Electrolyte Buffer/Wash Solution



В

 Sample or Reference/Diluted ISE Electrolyte Buffer (CX7 DELTA System)

Figure 3-56. Flow Mixers

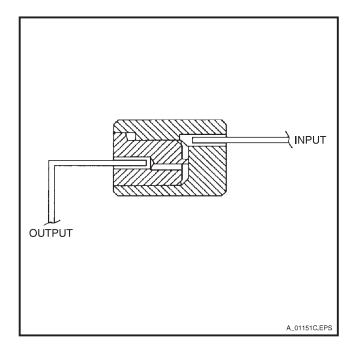
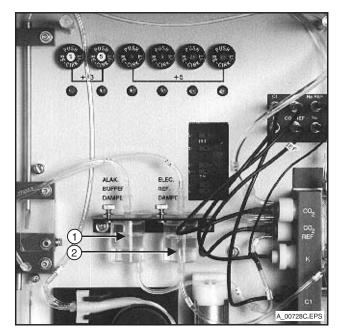


Figure 3-57. Flow Mixer Port Orientations

3.4.11 Damper Assemblies

Two damper assemblies are located side-by-side and just to the left of the flow cell. The damper to the left contains Alkaline Buffer reagent, while the damper to the right contains ISE Electrolyte Reference reagent (Figure 3-58). The purpose of the damper assemblies is two-fold: 1) to eliminate pumping pulsations created by the peristaltic pumps and, 2) to prevent bubbles from entering the flow cell.

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- 1 Alkaline Buffer Damper Assembly
- 2 Electrolyte Reference Damper Assembly

Figure 3-58. Damper Assemblies

3.4.12 Peristaltic Pump Assembly

Ten stepper motor-driven peristaltic pumps (peripumps) (Figure 3-59) are employed for: transporting reagents and wash solution to the flow cell and the chemistry reaction cups, sipping and draining the reaction cups, and washing and draining the electrolyte injection cup. The function of each pump, from left to right, is described below.

Pump 1	Sips and drains the glucose and crea-
	tinine reaction cups

- Pump 2 Sips and drains the BUN and calcium or total protein reaction cups.
- Pump 3 Delivers Alkaline Buffer reagent to the CO₂ measurement and reference electrodes in the flow cell (after passing through the alkaline buffer damper assembly) and returns the recycled alkaline buffer to the reagent bottle.
- Pump 4 Delivers undiluted ISE Electrolyte Reference solution to the reference electrode in the flow cell (after passing through the electrolyte reference damper assembly).
- Pump 5 Transports wash solution to the electrolyte injection cup during cleaning of the exterior of the probe.

Pump 6 Delivers BUN reagent and wash solution (for diluting the reagent in a ratio of 1:5) to the glucose reaction cup.

Pump 7 Delivers glucose reagent and wash solution (for diluting the reagent in a ratio of 1:5) to the glucose reaction cup.

Pump 8 Deliver calcium reagent to the calcium reaction cup or total protein reagent to the total protein reaction cup.

Pump 9 Delivers creatinine reagent to the creatinine reaction cup.

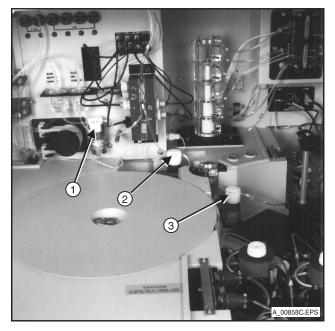
Pump 10 Located below the damper assemblies, drains waste from the electrolyte injection cup.



Figure 3-59. Peristaltic Pump Assemblies

3.4.13 Solenoid Valves

Three discrete solenoid pinch valves operate in conjunction with the ratio pump and pinch valve "E" to control the movement of solution throughout the electrolyte reagent system (Figure 3-60). Separate valves are used to regulate the flow of alkaline buffer, diluted electrolyte buffer and the draining of the electrolyte injection cup. Under microprocessor control, the valves open and close at predetermined intervals during the analysis cycle to ensure accurate and precise transportation of these reagents.



- 1 Alkaline Buffer Solenoid Valve
- 2 Flow Cell Solenoid Valve
- 3 Electrolyte Injection Cup Solenoid Valve

Figure 3-60. Solenoid Valves

3.4.14 Electrolyte Injection Cup

The electrolyte injection cup functions both as a mixing station for sample and buffer prior to their delivery to the flow cell, and as a wash station for the pickup probe. As illustrated in Figure 3-61, the electrolyte injection cup includes two inlet ports (one for wash solution and one for diluted electrolyte buffer), a rubber quad-ring in combination with a colored spacer (washer), which form a seal with the pickup probe collar for addition of sample or reference, and two outlet ports (one to the flow cell and one to the drain).

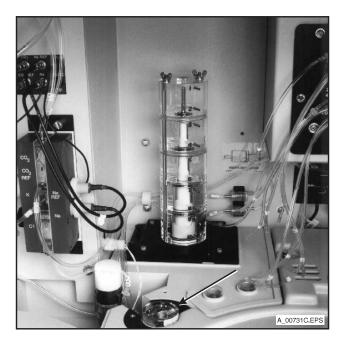


Figure 3-61. Electrolyte Injection Cup (EIC)

3.4.15 Flow Cell Assembly

The flow cell assembly houses the six or seven electrodes (four or five measurement and two reference) used in the analysis of electrolytes. Located at the front of the flow cell are two inlet ports. The lower port admits ISE Electrolyte Reference solution to the reference electrode while the upper port supplies CO₂ Acid Reagent to the previously diluted sample stream. The Alkaline Buffer solution is routed past the CO₂ reference and measuring electrode and then recycled into the Alkaline Buffer solution bottle.

Situated in the middle of the flow cell is a porous carbon bridge (or reference junction). The carbon bridge provides an electrical contact between the ISE Electrolyte Reference solution and the diluted sample stream to reduce signal interferences that are due to electrical noise. After analysis, the ISE Electrolyte Reference solution and diluted sample exit the flow cell through the two top outlet tubes to the drain assemblies. The location of the electrodes and solution ground connections is shown in Figures 3-62 and 3-63.

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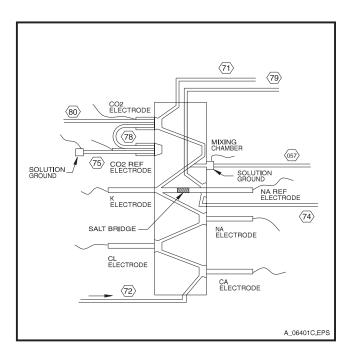


Figure 3-62. CX4/CX7 DELTA Flow Cell Assembly

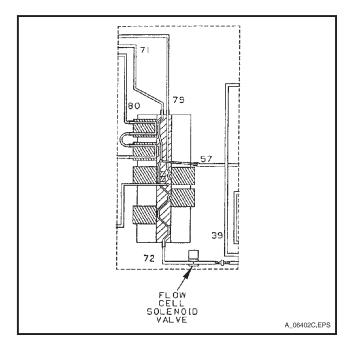


Figure 3-63. CX4CE/CX7 Flow Cell Assembly

3.4.16 CX3 Reagent Compartment

The CX3 reagent compartment is located directly below the mechanical assemblies (Figure 3-64). The compartment houses the following electrolyte reagents:

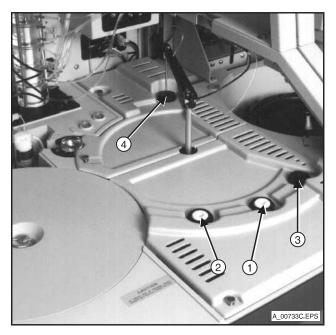
Wash Solution
ISE Electrolyte Buffer
CO₂ Acid Reagent
ISE Electrolyte Reference
BUN Reagent
CO₂ Alkaline Buffer
Calcium or Total Protein Reagent
Glucose Reagent
Creatinine Reagent



Figure 3-64. CX3 Reagent Compartment

3.4.17 CX3 Chemistry Reaction Modules

There are four chemistry reaction modules; each module is specific for a particular chemistry (Figure 3-65). The four chemistries are: glucose, urea nitrogen (BUN), calcium or total protein and creatinine. The calcium or total protein and creatinine modules are similar except for the filters used in the detector assemblies and the temperature settings. The urea nitrogen and glucose reaction modules are identical except for the sensors used for their respective measurements.



- 1 GLU3
- 2 BUN3
- 3 CA3 or TP3
- 4 CRE3

Figure 3-65. Chemistry Reaction Modules

3.5 ELECTRONIC/CIRCUIT BOARD COMPARTMENT

WARNING

Always turn the appropriate circuit breaker off before performing any service on the mechanical or electronic assemblies.

CX4

The electronic/circuit board compartment (Figure 3-66) located behind the upper front panel of the CX4 analyzer houses the main electronic/circuit boards needed for system operation.

The compartment consists of a slotted-card cage, multibus backplanes, and power distribution board. Individual boards slide into the card cage frame and insert into the edge connectors of the backplane. The primary function of the major electronic boards situated in the card cage can be identified as follows:

A. Analog-to-Digital Converter (ADC) Board —the ADC board receives commands from the master analog controller board. Its primary function is to receive all analog signals originating from the photometer and convert them to a digital value.

- B. Master Analog Controller (MAC) Board —the MAC board accepts commands and data from the host computer board. It is responsible for controlling the ADC conversion process, measuring and computing absorbance data, and transmitting the reduced data to the CPU board.
- C. System Interface Board —this multi-function board serves several purposes: 1) provides the digital-to-analog circuitry for the xenon lamp source, 2) provides reagent bar code reader circuitry, and 3) provides circuitry for the various sensors (example, reagent compartment door, fluid level sensors) used on the instrument.
- D. Power Status 4 Board —the status board monitors the various power supply voltages and provides an interface to the heater controller boards, allowing temperatures to be set and monitored. In addition, the board contains a battery-backed real-time clock. On CX7 only, this board also interfaces the CX3 module and CX4 MMC sample carousel position and probe clear signals.
- E. Memory Board —a dynamic memory board provides up to four megabytes of random access memory (RAM), which is used for storage and retrieval of operating program information and other pertinent data.
- F. Central Processing Unit (CPU) Board —the main computer board of the instrument is a Z8001 microprocessor. The CPU board coordinates all CX4 motion, interfaces with the user through the system console (PC), and calculates answers to all CX4 tests.
- G. Heater Control Boards (3) —responsible for temperature sensing, setting, and control of each thermally controlled area of the instrument.
- H. Master Motion Controller (MMC) Board interfaces the CPU to the motor system controller boards. Upon receiving commands from the host CPU, the MMC board forms the overall motion scheme, breaks the motion into individual motor commands, and disseminates the motor commands to the individual motor system boards.
- I. Motor System Controller (MSC) Boards (5) the motor system controller boards, which receive instructions from the master motion controller board, provide the control needed to drive the various stepper motors and solenoid valves used in the CX4 system. The five boards

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- on the system are identical in construction and are housed in the card cage on the right-hand side.
- J. SCSI (Small Computer Systems Interface)
 Communication Board —establishes the main
 communication link of the electronics of the
 system console (PC), the CX3 (CX7 users
 only), and the CX4. The interface is connected
 to the PC through a flexible cable. CX7 users
 will have a second flexible cable which
 connects the interface to the CX3.

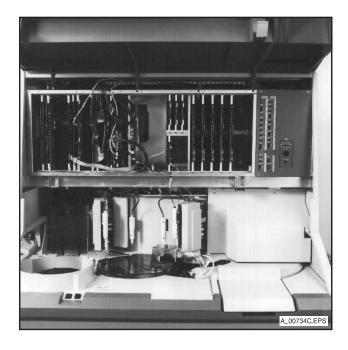


Figure 3-66. Electronic/Circuit Board Compartment (CX4)

All changes and repairs to these boards should be by or with the direction of a Beckman Representative.

CAUTION

To avoid damage to boards, never remove or replace a circuit board unless the MAIN circuit breaker has been turned off.

CX3 (CX7 Users Only)

The CX3 electronic/circuit board compartment (Figure 3-67) is located behind the cover on the upper portion of the analyzer. The compartment houses the circuit boards necessary for system operation. The following boards are included:

- A. Analog (ANL) Board —provides the electronic interface between the electrodes (six or seven electrolyte electrodes and four cup chemistry electrodes) and the Analog-to-Digital Converter (ADC) Board. There are three ANL boards: one for the sodium, potassium, chloride, calcium (ISE), and carbon dioxide electrodes, the second for the BUN and glucose electrodes and the third for the creatinine and calcium or total protein electrodes. The board contains high impedance buffers for the electrodes, which allows measurement of absolute potential or differential voltage using reference electrodes.
- B. Analog-to-Digital Converter (ADC) Board responsible for multiplexing all signals originating from the analog board and converting them to a digital value.
- C. Central Processing Unit (CPU) Board —the main computer board of the CX3. The CPU board coordinates all instrument motion, interfaces with the user through the system console (PC), and calculates answers to all chemistry tests.
- D. Memory (RAM) Board —Data from various measurements are stored on the memory board. The RAM also contains general processing and programming routines to convert the data for presentation on the video display (CRT).
- E. Master Motion Controller (MMC) Board provides the system with all the functions required to control and monitor all motors and motor sensors.
- F. Motion Driver #1 Board (MD1) —provides circuits necessary to drive stepper motors, AC synchronized motors, and the individual solenoid valves. The mechanical subsystems that the MD1 board serve include: crane assembly, ratio pump, pinch valve, peri pumps, and solenoids.
- G. Motion Driver Board (MD2) —functions the same as MD1. The mechanical subsystems that the MD2 board serve include:
 - Analog Board
 - 2. ADC Board

- 3. Master Motion Controller Board
- 4. Motion Driver Board.

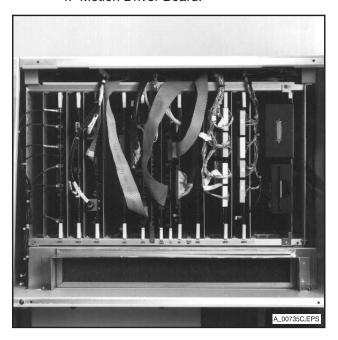


Figure 3-67. CX3 System Electronic/Circuit Board Compartment

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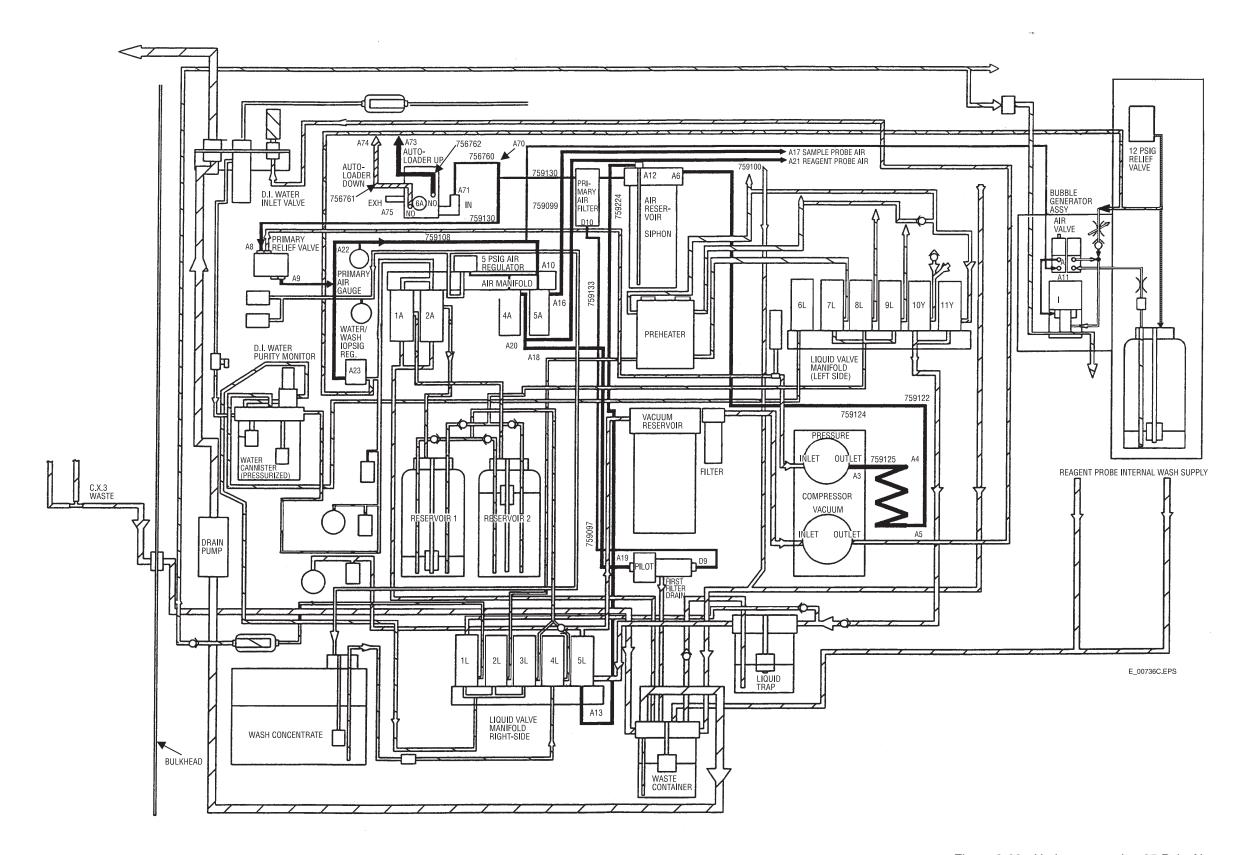


Figure 3-68. Hydropneumatic - 25 Psig Air

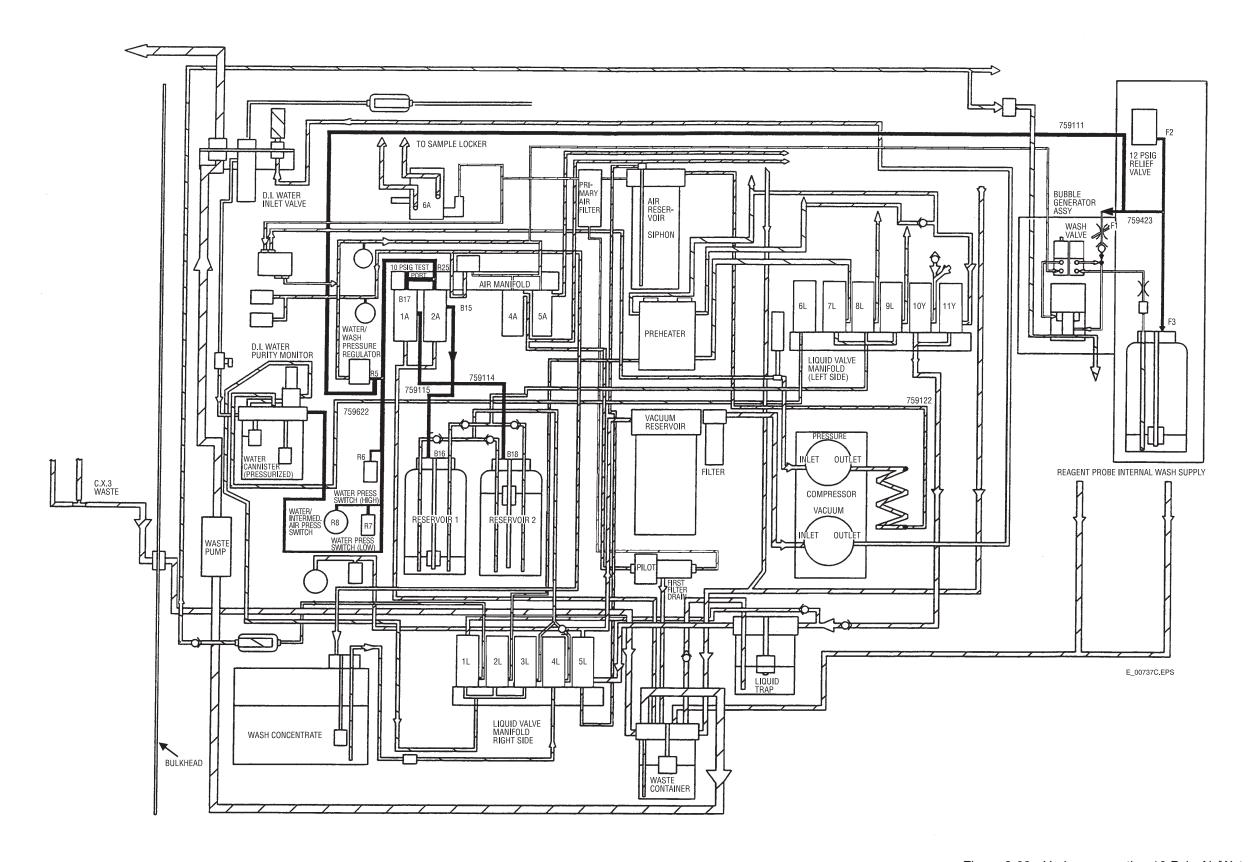


Figure 3-69. Hydropneumatic - 10 Psig Air/Water/Wash

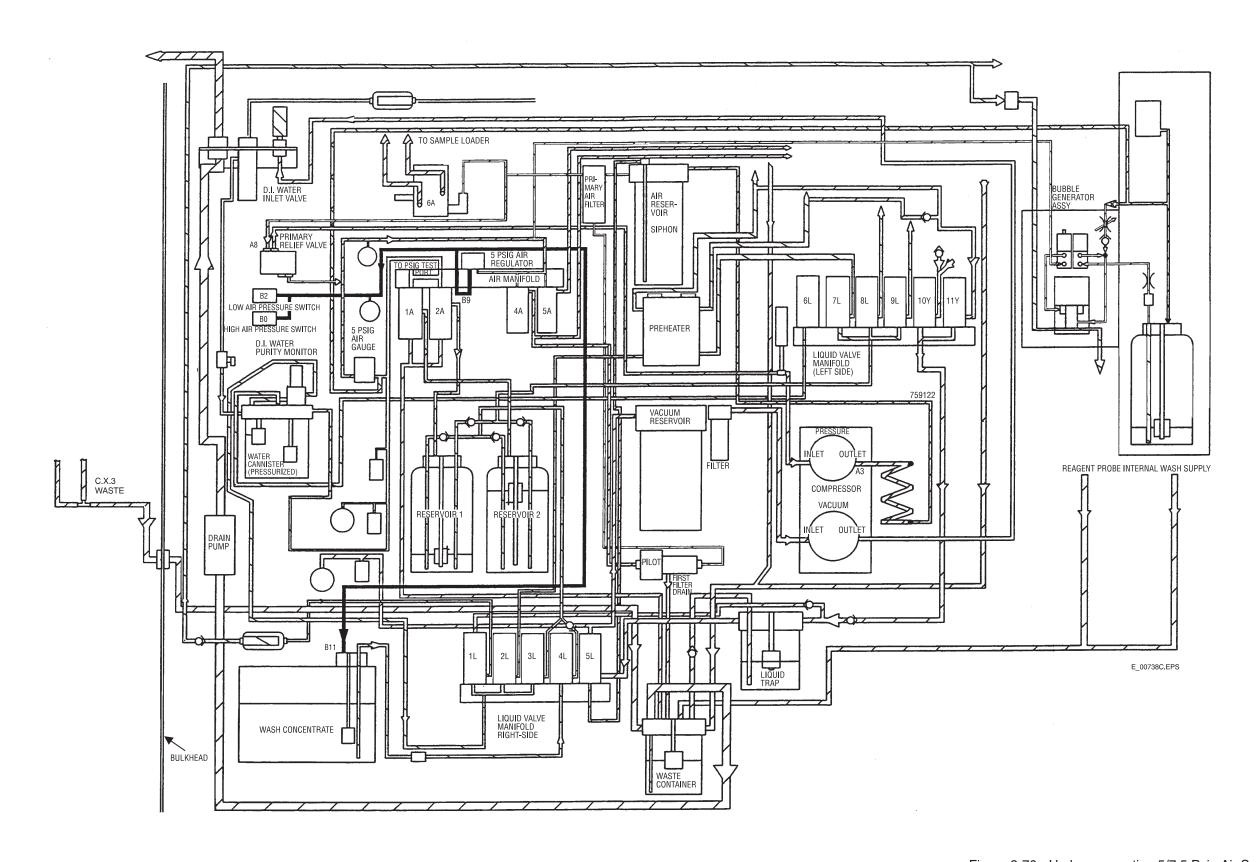


Figure 3-70. Hydropneumatic - 5/7.5 Psig Air System

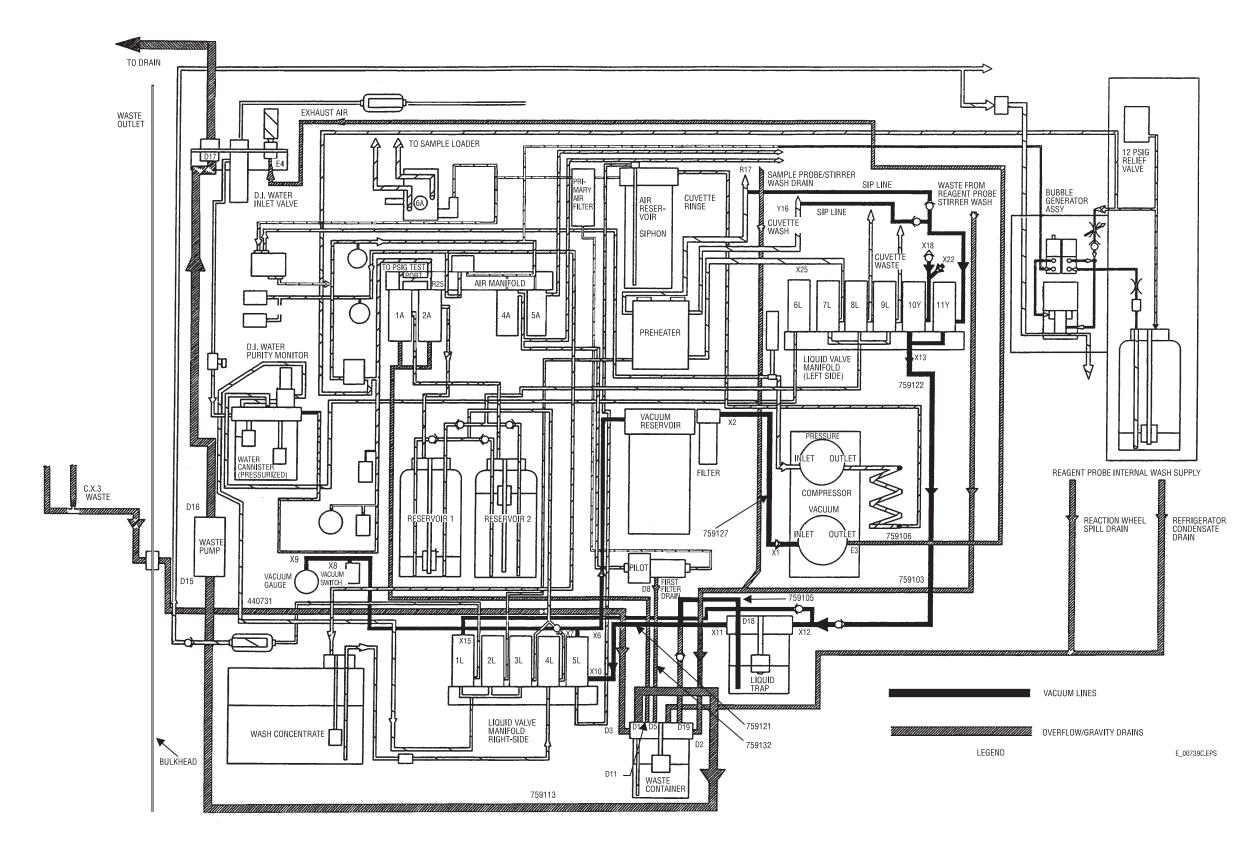


Figure 3-71. Hydropneumatic - Vacuum/Waste

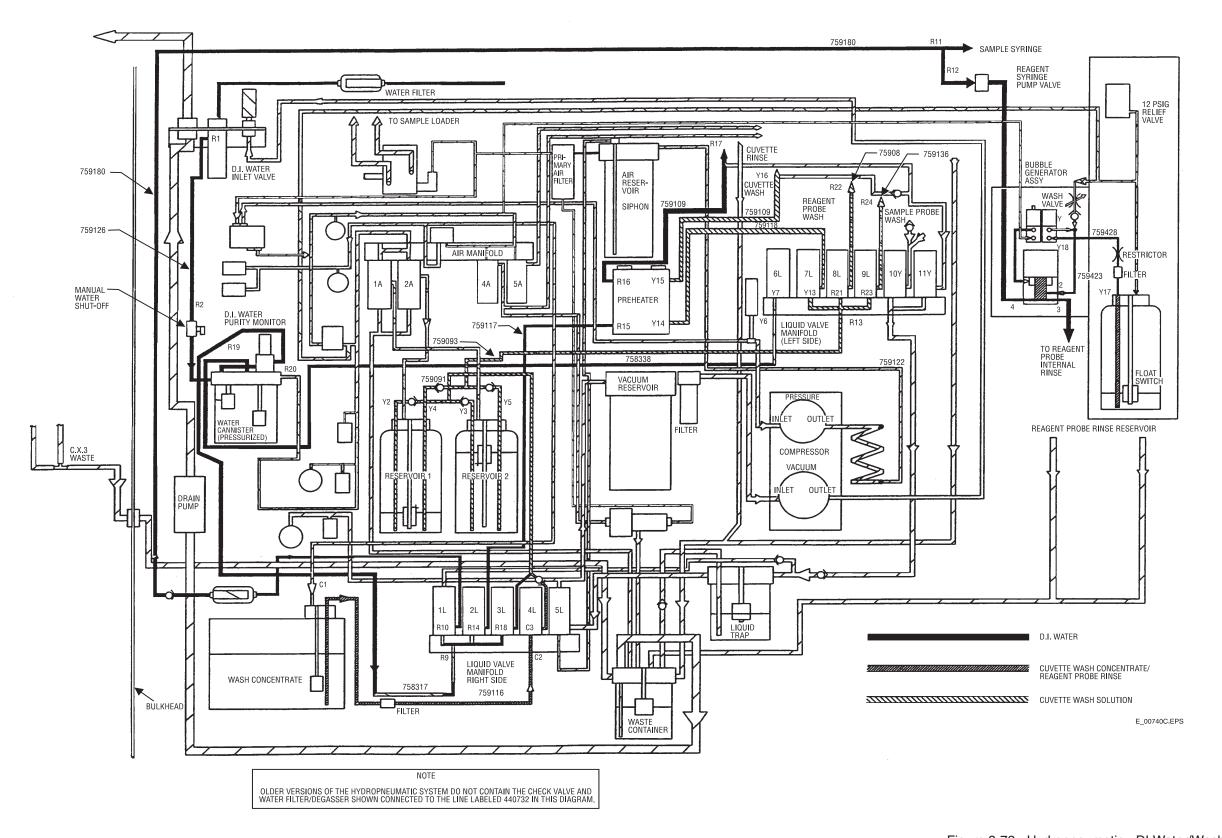


Figure 3-72. Hydropneumatic - DI Water/Wash

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Section 4 PRINCIPLES OF OPERATION

4.1 OPERATIONAL OVERVIEW

The SYNCHRON CX7/CX7 DELTA System is a discrete, random access clinical analyzer capable of performing a wide variety of chemistry tests in a single run. The analyzer performs only those tests programmed by the operator. All system functions are totally automated and under control of the onboard microprocessors.

CX4

The unique design of the optical system of the CX4, enables different types of analyses to be performed simultaneously. Kinetic, endpoint, and nonlinear analysis can be done concurrently.

CX3

The Ion selective electrodes, housed in a flow cell, measure sodium, potassium, chloride, and calcium using indirect potentiometry. In addition, carbon dioxide is measured via pH electrodes. The CX3 has four reaction cups, each of which are used in the determination of distinct chemistries. Two colorimetric reaction cups measure total protein (or calcium) and creatinine bichromatically. Urea nitrogen is measured by a conductivity electrode, and glucose is measured with a polarographic electrode.

A description of how each major component functions as a separate unit was presented in Section Three. This section presents an explanation of how these components function as an integrated unit, as well as a discussion of signal processing and data acquisition.

4.2 SAMPLE AND REAGENT PROCESSING

Once programming has been completed on each sample, and the operator has placed the sample sectors onto the autoloader assembly, the only action then required is to press **START** to initiate the analysis process. In the operational state, a number of events occur simultaneously and are under direct control of the instrument microprocessors.

The sequence of events involved in processing samples and reagent are discussed in the following paragraphs.

4.2.1 Analytical Spin Cycle

Basic to the operation of the instrument is the concept of the analytical spin cycle. A spin cycle occurs every 16 seconds when the instrument is in the operational state; it involves the clockwise rotation of the 80-position cuvette reaction wheel at a speed of 90 rpm for approximately 6 seconds. During this time, each cuvette passes through the optics station where continuous absorbance readings are measured, flash-corrected and recorded for up to five different wavelengths.

At the completion of the spin cycle, each cuvette is indexed one position counterclockwise. In this way, a single cuvette can rotate around the entire circumference in 22 minutes, moving through the designated reagent and sample addition stations, through the incubation phase and finally through the wash station, where the cuvettes are prepared for the next sequence of analyses.

4.2.2 Service Interval

A service interval occurs in the interim time (10 seconds) between spin cycles. Included among the several important functions coordinated to take place during the service interval are:

- 1. processing of cuvettes by the wash station between alternate spin cycles and mixing,
- primary or secondary reagent addition and mixing,
- 3. sample addition and mixing.

4.2.2.1 Cuvette Washing

Pressing **START** begins operation of the system. Initially, (if the system has been left idle for 12 or more hours, or if the system has gone through a reboot process) the cuvettes are processed by the wash station (Figure 4-1) in preparation for new reagent addition. (Refer to Paragraph 3.4.3.3, Cuvette Wash Station, for a complete description.)

NOTE

If idle time has not exceeded 12 hours or if a reboot has not occurred, reagent addition will begin immediately without waiting for cuvettes to be washed. However, washing will continue with the remaining cuvettes.

The six cuvette washer probes are divided by function into pairs. At the beginning of the wash procedure, the probes are lowered into separate cuvettes. Each of the three pairs of probes simultaneously perform a separate function on two cuvettes as follows:

- Probes 1 and 2 remove the reaction products followed by the addition of wash solution.
- Probes 3 and 4 remove the wash solution followed by the addition of deionized water.
- Probes 5 and 6 remove the deionized water alternately using a vacuum followed by forced air. These probes are equipped with a special square wiper-nozzle tip whose dimensions fit the inner diameter of the cuvette. These wipers serve to remove the deionized water and any residual fluid adhering to the inner walls.

When complete, two spin cycles occur allowing each cuvette to rotate to the next pair of probes. When a cuvette has passed through the three wash stages, it is ready to be used for analysis.

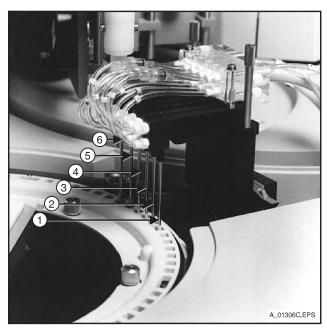


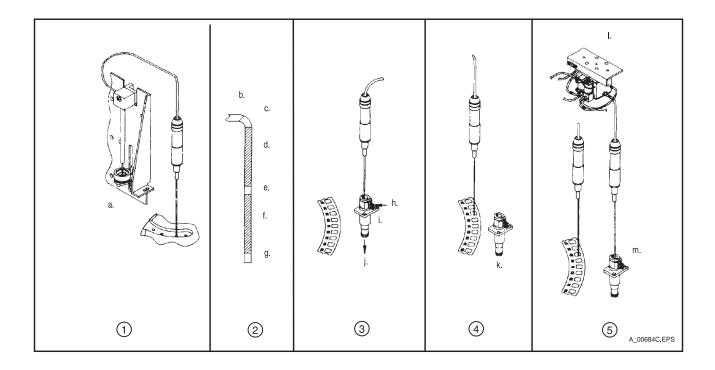
Figure 4-1. Cuvette Washer Assembly

4.2.2.2 Reagent Addition

Following completion of all three wash stages, the cuvettes continue to rotate towards the reagent addition position at the completion of each spin cycle. When the first cuvette has rotated into position, the reagent addition sequence is initiated. The reagent delivery sequence follows (Figure 4-2):

- The reagent crane rotates into a position directly above the reagent carousel. The reagent carousel, which holds a maximum of 24 reagent cartridges, rotates the designated reagent cartridge into position for pickup.
- 2. A 6 μ L air slug is drawn into the probe as it lowers into the first cartridge compartment. The probe lowers into the reagent until the reagent level is sensed then proceeds to aspirate the appropriate volume. The probe then retracts from the cartridge, and in the process, draws in a 3μ L air slug.
- 3. The crane rotates to the wash cup where the probe is lowered momentarily to clean its exterior surface. If the chemistry requires a second reagent, the probe rotates to the second reagent compartment and the appropriate volume is aspirated (as above) followed by another 3 μL air slug. The crane again moves to the wash cup to clean its exterior surface.
- 4. From the wash cup, the crane rotates the probe into position directly above the cuvette. The probe is lowered into the cuvette and the reagent(s) dispensed. Once the reagent has been dispensed, the probe is raised out of the cuvette and the reagent mixer moves to the cuvette and is activated for approximately 1.0 second.
- 5. After dispensing is completed, the reagent probe is lowered into the wash cup. During this time, diluted wash concentrate cleans the exterior probe surface and an intermixed, air bubbles, probe rinse solution stream is delivered through the flow line attached to the top of the probe, which serves to clean the interior surface.

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- 1 Aspirate Reagents from Carousel.
 - a Reagent Syringe
- 2 Sequence of Reagent Pickup. Note: Outside of Probe Cleansed Between Pickup of RGT A and B.
 - b Distilled Water

 - c 6 µL Air Slug d Primary RGT A

 - e 3 µL Air Slug f Primary RGT B
 - g 3 μL Air Slug
- 3 Cleanse Probe Exterior.
 - h Forced Jets of Wash
 - i Wash Cup
 - j Drain
- 4 Inject Reagents into Cuvette. k Wash Cup
- 5 Internally Rinse with DI Water, Air Scrub, and Probe Rinse Solution
 - + 1.0 Sec. Stirring of Sample Cuvette.
 - I Bubble Generator
 - m Wash Cup

Figure 4-2. Reagent Probe Sequence

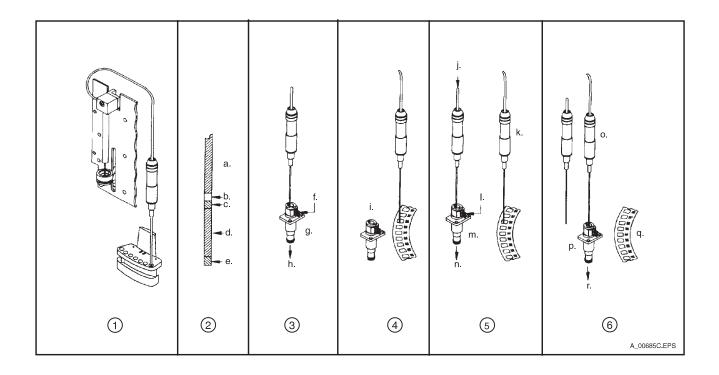
4.2.2.3 Sample Addition

Once reagent addition has occurred, the cuvettes continue to index towards the sample addition position every spin cycle. The addition of sample to the reaction cuvette occurs approximately 6 minutes (20 cycles) after reagent addition. During this time, the previously dispensed reagent equilibrates to 37°C or 30°C within the temperature-controlled reaction wheel. This delay also provides for sufficient time to perform reagent blank readings on the primary reagent(s). The sequence of sample addition follows (Figure 4-3):

- 1. The sequence begins with the pickup probe rotating to the sample wheel and lowering into the sample tube or cup. A 1 μ L air slug is aspirated before the probe is lowered into the sample cup. This serves to separate the deionized water in the pickup line from the sample. The probe then lowers into the cup until the level sense mechanism detects the surface of the sample. The probe is lowered slightly below the surface and the appropriate volume of sample required for a test plus a 1.6 μ L (1 μ L before the sample and 0.6 μ L after the sample) scrub sample is aspirated.
- 2. The probe is raised out of the sample and the level sense mechanism reset. The probe is then lowered a second time to the point of sample aspiration in Step 1. The level sense is engaged. If no sample is detected on the second dip, any sample which was aspirated is discarded and the operator alerted to a "NO SAMPLE DETECTED" condition. This process ensures that there was sufficient sample aspirated to complete the test.

- 3. Following successful sample aspiration, the probe rises out of the sample tube or cup and proceeds to the wash cup. In the wash cup, the exterior surface of the probe is cleaned by the forced jet of diluted wash concentrate and 0.5 μ L of scrub sample is dispensed. The sample crane then raises the probe from the wash cup and rotates to a position directly above the cuvette.
- 4. The probe lowers into the cuvette and the appropriate volume of sample is dispensed.
- 5. The probe then returns to the wash cup for internal and external cleaning. The additional 1 μL scrub sample is discarded. During this time the sample mixer rotates to the cuvette, where it is lowered and activated for a period of 1.0 second.
- 6. The mixer is then raised from the cuvette and rotated to the wash cup for cleaning.

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- 1 Aspirate Sample from Carousel.
- 2 Sample Aspiration.
 - a DI Water
 - b 1 μL Air Slug
 - c 1 μL Scrub Sample
 - d Sample
 - e 0.6 μL Scrub Sample
- 3 Clean Probe Exterior + 0.5 μ L Sample Dispensed.
 - f Forced Jets of Wash
 - g Wash Cup h Drain
- 4 Deliver Sample to Cuvette.
 - i Wash Cup
- 5 Probe Cleaned Internally and Externally with DI Water + 1.0 Sec. Mixing of Sample Cuvette.
 - j Forced Stream of DI Water
 - k Mixer
 - I Forced Jets of Wash Cup
 - m Wash Cup
 - n Drain
- 6 Mixer Washed.
 - o Mixer
 - p Wash Cup
 - q Spin
 - r Drain

Figure 4-3. Sample Probe Sequence

4.3 CHEMISTRY SCHEDULING

One of the unique features of the SYNCHRON CX7/CX7 DELTA is that in addition to being able to continuously load routine samples, the user may calibrate or add STAT samples while the system is running. As a result, the samples placed on the system must be prioritized based on what is programmed. The processing schedule of the chemistries programmed occurs at the time a sector is loaded onto the sample carousel and successfully read by the bar code reader. This generates a "test list" prioritized using the following guidelines:

- Sample priority: STAT tests > Calibration > Routine tests
- 2. Within any single sample, the tests programmed are scheduled for optimal throughput such that chemistries with the longest assay (reaction) time will be run first. If more than one test has the same assay time, scheduling is random with respect to each other for those tests

The test list, therefore, is a priority queue, with STAT tests being the highest priority, calibrator tests being the second highest priority, and routine tests being the lowest priority. The scheduler scans the test list, starting at the top, when looking for a test to start. If it runs across a test that cannot be run, the test is removed from the list, and the test is flagged on the printed report. Examples of the flags are: CHEMISTRY BYPASSED, REAGENT NOT ON BOARD, CALIBRATION FAILED, etc.

When a CX4 calibration is requested while the system is in operation, the scheduler will continue to use the previous calibration for that reagent cartridge until the sector containing the calibrators has been loaded onto the sample carousel. Once loaded, the calibrator tests are placed on the top of the test list and processed first so that all subsequent tests for that reagent will be based on the new calibration. Note that since STAT tests are of a higher priority than calibrator tests, some STAT requests may be taken off of the test list because there is no valid calibration for the chemistry, even though the calibrator tests for the chemistry are in the test list and ready to run. Non-STAT tests for the same chemistry, being of lower priority than calibrator tests, will be deferred until the calibrator tests have been started.

Once the tests have been processed, the result reports will be printed in the order completed which may or may not be in sample order.

4.4 CX3 SAMPLE AND REAGENT FLOW

The CX3 provides the capability of sodium, potassium, chloride, calcium (ISE or Cup), CO₂, glucose, total protein, creatinine and urea nitrogen (or urea) testing. Patient samples, controls, and calibrators programmed for these tests are processed in a similar manner and handled separately by the reagent and sample system of the CX3 module. (Refer to Paragraphs 4.4.1, Electrolytes for details.) Refer to Figures 4-21 and 4-22 for CX3 DELTA and CX3 System Reagent Flow Diagrams.

4.4.1 Electrolytes Samples and Reagent Flow

NOTE

This section describes sample and reagent flow for the electrolytes. It is important to remember that electrolyte measurements are concurrent with cup chemistries, even though the two types are presented separately for simplicity.

The sequence of operation presented in Figures 4-4 through 4-15 is detailed below. Figures 4-4, 4-6, 4-8, 4-10, 4-12, and 4-14 refer to CX3 (DELTA), while Figures 4-5, 4-7, 4-9, 4-11, 4-13, and 4-15 refer to CX3.

- 1. At the appropriate scheduled interval, the sample wheel rotates and aligns the designated sector into position for aspiration. The sample crane moves the pickup probe over the sample tube or cup. During a brief hesitation before the probe enters the cup, a 3 µL air slug is drawn into the probe to displace the ISE Electrolyte Reference solution which is resident in the pickup probe. The probe enters the sample and aspirates 7 µL of scrub sample. The probe retracts from the sample, and in the process, aspirates an additional 4 µL air slug. The probe re-enters the sample and the appropriate volume of sample is drawn into the probe by the top cylinder of the ratio pump. The ratio pump draws concentrated ISE Electrolyte Buffer in cylinder 2, concentrated CO2 Acid Reagent in cylinder 3, and DI water in cylinders 4 and 5. At the same time, peristaltic pump 2 delivers fresh ISE Reference to the reference electrode for the sample read comparison.
- Following sample pickup, the probe retracts from the sample and the crane rotates to the electrolyte injection cup (EIC). The probe is lowered to make a pressure seal within the cup. Peristaltic pump number 1 starts to supply Alkaline Buffer to the CO₂ electrodes, if electrolytes are ordered.

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NOTE

The Alkaline Buffer Reagent is recycled through one portion of the drain assembly and back into the reagent bottle through the action of the peristaltic pump and gravity drain line.

When electrolytes are requested, peristaltic pump number 4 delivers ISE Electrolyte Reference solution to the reference electrode for Na, K, CL, and Calcium (ISE). The ratio pump moves up allowing dilution of the concentrated ISE buffer and CO_2 Acid with Wash Solution in the in-line mixing chambers. The diluted ISE Buffer is then delivered to the EIC to be mixed with the 62 μ L of sample while the diluted Acid Reagent is sent to the flow cell.

 Sample which is now diluted 1:20 with Buffer is sent through a flow mixer (DELTA) to the flow cell for analysis of Na, K, Cl, and Calcium (ISE). It is then further diluted with Acid Reagent (1.3:1) for measurement of CO₂.

NOTE

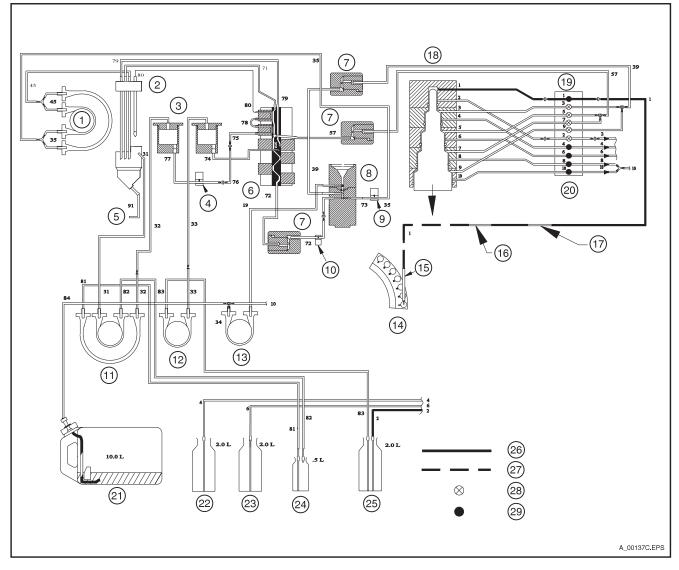
Only the last 30% of this mixture is measured by the electrodes. The first part (70%) provides for additional washing action to prevent any possible sample carryover and allows the electrodes to stabilize for accurate reading.

At this point, the Alkaline Buffer peri-pump is turned off after supplying approximately 2 mL of reagent to the CO₂ electrodes.

After electrolyte sample injection, the flow cell solenoid valve closes and the sample crane moves up. Peristaltic pump number 5 delivers Wash Solution to the EIC and the probe then moves down to an intermediate position. The ratio pump then moves up and pushes out a small amount of sample. This sequence washes the exterior of the probe and prevents back contamination of Buffer into any remaining sample for cup chemistries. The EIC is drained to waste by peristaltic pump 10.

4. While the electrodes respond to the sample in the flow cell, the probe delivers sample to the cups and then returns to the EIC cup and dispenses excess sample, air and Reference solution. The EIC cup is drained to waste by peristaltic pump number 10.

- 5. Peristaltic pump number 3 is activated to deliver Alkaline Buffer to the CO₂ sample and reference electrodes. At the same time ISE Electrolyte Reference, concentrated ISE Electrolyte Buffer, concentrated CO₂ Acid Reagent, and Wash Solution are again drawn into the ratio pump and peristaltic pump number 4 delivers fresh ISE Reference to the reference electrode.
- 6. Similar to the sample measurement interval described in Steps 2 through 4, the 1:20 dilution of ISE Electrolyte Reference solution is measured. The delivery of this mix is in two steps; the first serves to rinse the sample probe and flow cell, the second step is the measurement of diluted Reference solution and is used to check and compensate for electrode drift and temperature changes.
- 7. During the reading interval for the measuring electrodes, ISE Electrolyte Reference is also measured by the sodium reference electrode. Both the diluted sample and the diluted reference readings are compared to the reference signal of the sodium reference electrode to compensate for small electrical noise or temperature variation by common-mode rejection analysis.



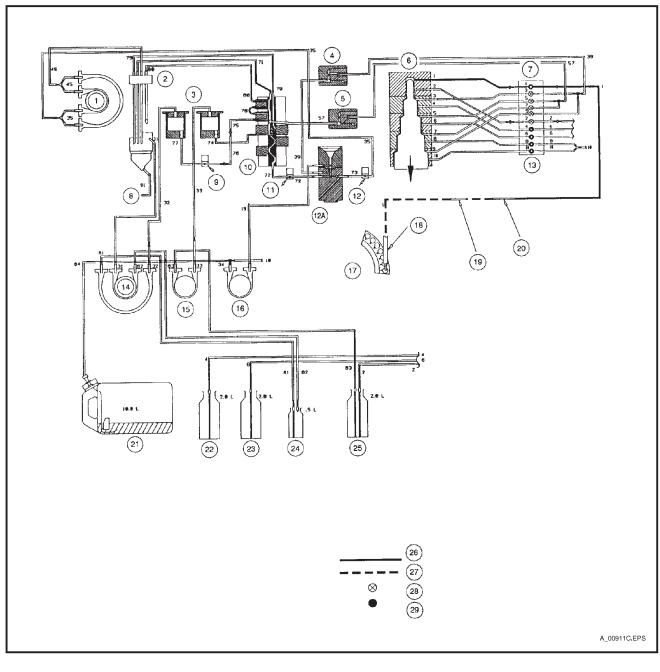
- 1 EIC Drain
- 2 Electrolyte Drain
- 3 Fluid Dampers
- 4 Alkaline Buffer Solenoid Valve
- 5 Drain
- 6 Flow Cell
- 7 Flow Mixer
- 8 EIC

- 9 EIC Drain Solenoid Valve
- 10 Flow Cell Solenoid Valve
- 11 Alkaline Buffer
- 12 Electrolyte Reference
- 13 EIC Wash
- 14 Sample Sector
- 15 Sample Probe
- 16 3 μL Air Slug

- 17 4 μ L Air Slug
- 18 Ratio Pump
- 19 Valve -E
- 20 Valve State: 2
- 21 Wash (Common Diluent)
- 22 Electrolyte Buffer
- 23 CO₂ Acid
- 24 CO₂ Alkaline Buffer
- 25 Electrolyte Reference
- 26 Electrolyte Reference
- 27 Sample
- 28 Valve Closed
- 29 Valve Open

Figure 4-4. CX3 DELTA Sample and Reagent Flow (Step 1)

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1 - EIC Drain

2 - Electrolyte Drain

3 - Fluid Dampers

4 - Flow Mixer 5 - Flow Mixer

6 - Ratio Pump

7 - Valve-E

8 - Drain

9 - Alkaline Buffer Solenoid Valve

10 - Flow Cell

11 - Flow Cell Solenoid Valve

12A - EIC

12 - EIC Drain Solenoid Valve

13 - Valve State: 2

14 - Alkaline Buffer

15 - Electrolyte Reference

16 - EIC Wash

17 - Sample Sector

18 - Sample Probe

19 - $3~\mu L$ Air Slug

20 - 4 μL Air Slug

21 - Wash (Common Diluent) 22 - Electrolyte Buffer

23 - CO₂ Acid

24 - CO_2 Alkaline Buffer

25 - Electrolyte Reference

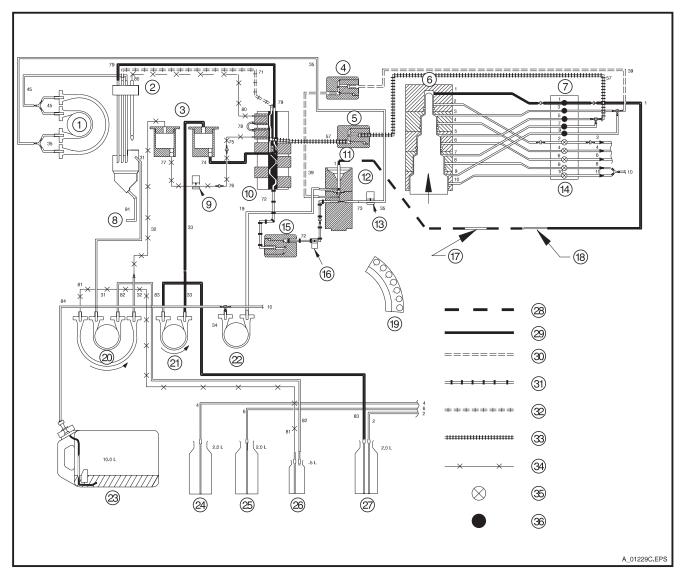
26 - Electrolyte Reference

27 - Sample

28 - Valve Closed

29 - Valve Open

Figure 4-5. CX3 Sample and Reagent Flow (Step 1)

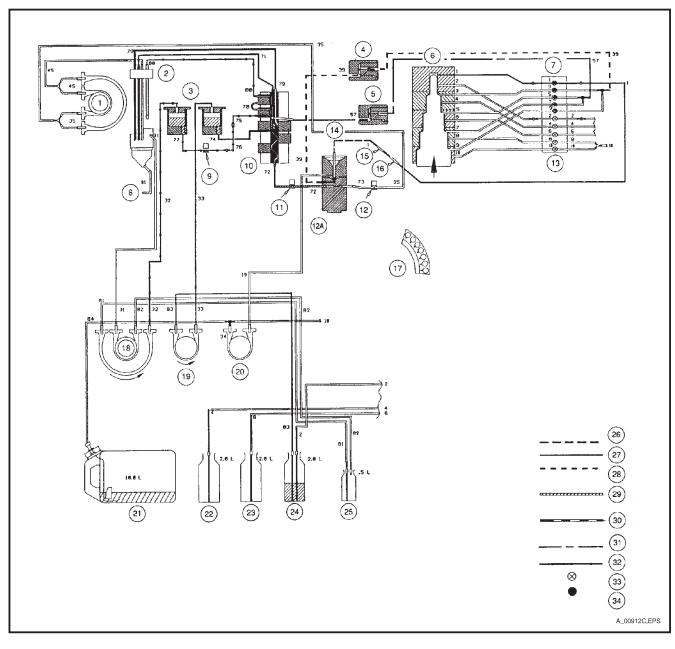


- 1 EIC Drain
- 2 Electrolyte Drain
- 3 Fluid Dampers
- 4 Flow Mixer
- 5 Flow Mixer
- 6 Ratio Pump
- 7 Valve-E 8 - Drain
- 9 Alkaline Buffer Solenoid Valve
- 10 Flow Cell
- 11 Sample Probe
- 12 EIC
- 13 EIC Drain Solenoid Valve
- 14 Valve State: 1
- 15 Flow Mixer
- 16 Flow Cell Solenoid Valve
- 17 Air Slug
- 18 Air Slug

- 19 Sample Sector
- 20 Alkaline Buffer
- 21 Electrolyte Reference
- 22 EIC Wash
- 23 Wash (Common Diluent)
- 24 Electrolyte Buffer
- 25 CO₂ Acid
- 26 ${\rm CO_2}$ Alkaline Buffer
- 27 Electrolyte Reference
- 28 Sample
- 29 Electrolyte Reference
- 30 Electrolyte Buffer/Wash Solution
- 31 Sample/Electrolyte Buffer Mixture
- 32 Sample/Electrolyte Buffer/CO₂ Acid Mixture
- 33 CO₂ Acid Reagent/Wash Solution
- 34 Alkaline Buffer
- 35 Valve Closed
- 36 Valve Open

Figure 4-6. CX3 DELTA Sample and Reagent Flow (Step 2)

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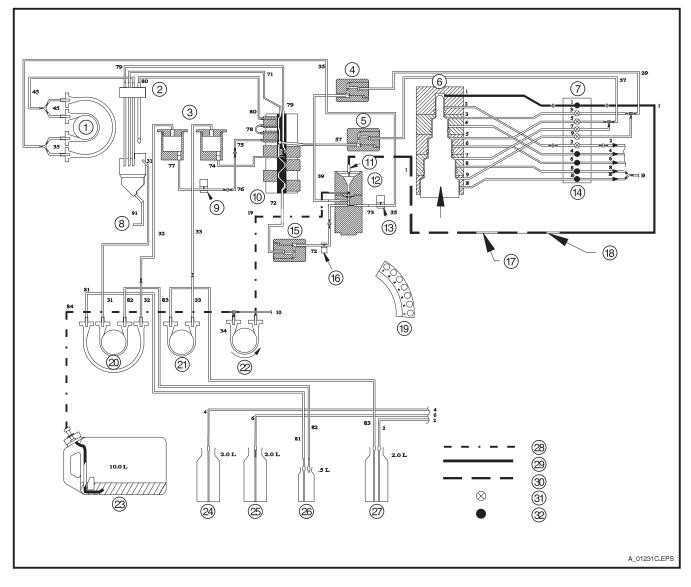


- 1 EIC Drain
- 2 Electrolyte Drain
- 3 Fluid Dampers
- 4 Flow Mixer
- 5 Flow Mixer
- 6 Ratio Pump 7 - Valve-E
- 8 Drain
- 9 Alkaline Buffer Solenoid Valve
- 10 Flow Cell
- 11 Flow Cell Solenoid Valve
- 12A EIC
- 12 EIC Drain Solenoid Valve
- 13 Valve State: 1
- 14 Sample Probe
- 15 Air Slug
- 16 Air Slug
- 17 Sample Sector

- 18 Alkaline Buffer
- 19 Electrolyte Reference
- 20 EIC Wash
- 21 Wash (Common Diluent)
- 22 Electrolyte Buffer
- 23 CO₂ Acid
- 24 Electrolyte Reference
- 25 CO₂ Alkaline Buffer
- 26 Sample

- 27 Electrolyte Reference
- 28 Electrolyte Buffer/Wash Solution
- 29 Sample/Electrolyte Buffer Mixture
- 30 Sample/Electrolyte Buffer/CO₂ Acid Mixture
- 31 CO₂ Acid Reagent/Wash Solution
- 32 Alkaline Buffer
- 33 Valve Closed
- 34 Valve Open

Figure 4-7. Sample and Reagent Flow (Step 2)

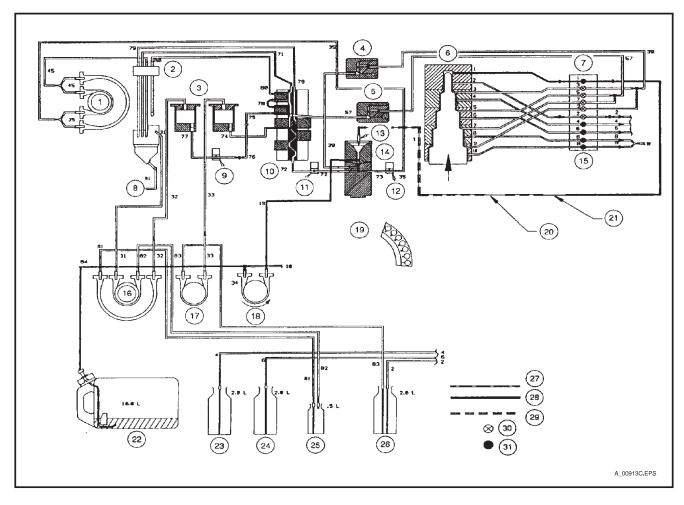


- 1 EIC Drain
- 2 Electrolyte Drain
- 3 Fluid Dampers
- 4 Flow Mixer
- 5 Flow Mixer
- 6 Ratio Pump
- 7 Valve-E 8 - Drain

- 9 Alkaline Buffer Solenoid Valve
- 10 Flow Cell
- 11 Sample Probe
- 12 EIC
- 13 EIC Drain Solenoid Valve
- 14 Valve State: 2
- 15 Flow Mixer
- 16 Flow Cell Solenoid Valve
- 17 3 μL Air Slug
- 18 4 μL Air Slug
- 19 Sample Sector 20 - Alkaline Buffer
- 21 Electrolyte Reference
- 22 EIC Wash
- 23 Wash (Common Diluent)
- 24 Electrolyte Buffer
- 25 CO₂ Acid
- 26 CO₂ Alkaline Buffer
- 27 Electrolyte Reference
- 28 Wash
- 29 Electrolyte Reference
- 30 Sample
- 31 Valve Closed
- 32 Valve Open

Figure 4-8. CX3 DELTA Sample and Reagent Flow (Step 3A)

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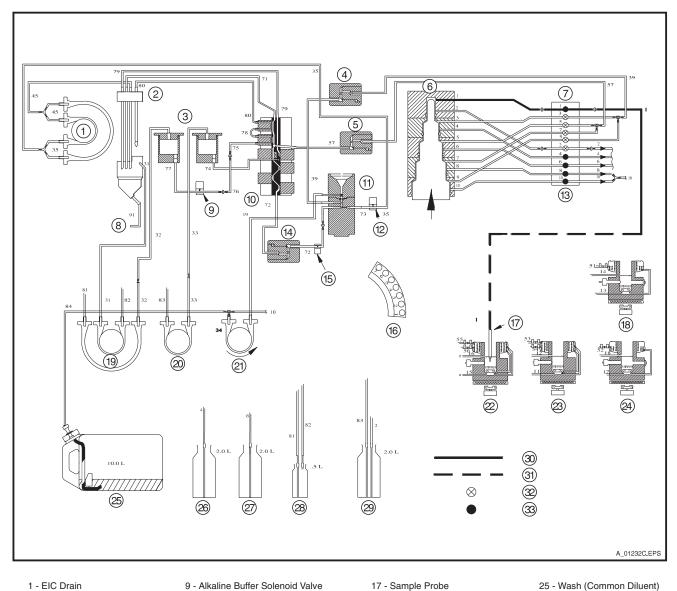
- 1 EIC Drain
- 2 Electrolyte Drain 3 Fluid Dampers
- 4 Flow Mixer
- 5 Flow Mixer
- 6 Ratio Pump 7 - Valve-E
- 8 Drain

- 9 Alkaline Buffer Solenoid Valve
- 10 Flow Cell
- 11 Flow Cell Solenoid Valve
- 12 EIC Drain Solenoid Valve
- 13 Sample Probe
- 14 EIC
- 15 Valve State: 2
- 16 Alkaline Buffer

- 17 Electrolyte Reference
- 18 EIC Wash
- 19 Sample Sector
- 20 3 μL Air Slug
- 21 4 μL Air Slug
- 22 Wash (Common Diluent)
- 23 Electrolyte Buffer
- 24 CO₂ Acid

- 25 CO₂ Alkaline Buffer
- 26 Electrolyte Reference
- 27 Wash
- 28 Electrolyte Reference 29 - Sample
- 30 Valve Closed
- 31 Valve Open

Figure 4-9. CX3 Sample and Reagent Flow (Step 3A)



- 1 EIC Drain
- 2 Electrolyte Drain
- 3 Fluid Dampers
- 4 Flow Mixer
- 5 Flow Mixer
- 6 Ratio Pump
- 7 Valve-E 8 - Drain

- 9 Alkaline Buffer Solenoid Valve
- 10 Flow Cell
- 11 EIC
- 12 EIC Drain Solenoid Valve
- 13 Valve State: 2
- 14 Flow Mixer
- 15 Flow Cell Solenoid Valve
- 16 Sample Sector

- 17 Sample Probe
- 18 CREA
- 19 Alkaline Buffer
- 20 Electrolyte Reference
- 21 EIC Wash
- 22 BUN
- 23 GLU 24 - CA/TP

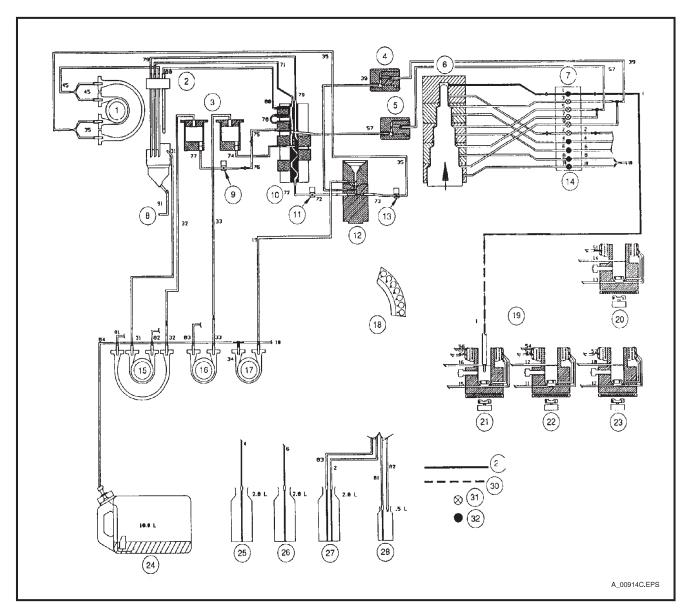
- 27 CO₂ Acid 28 - CO₂ Alkaline Buffer

26 - Electrolyte Buffer

- 29 Electrolyte Reference
- 30 Electrolyte Reference
- 31 Sample
- 32 Valve Closed
- 33 Valve Open

Figure 4-10. CX3 DELTA Sample and Reagent Flow (Step 3B)

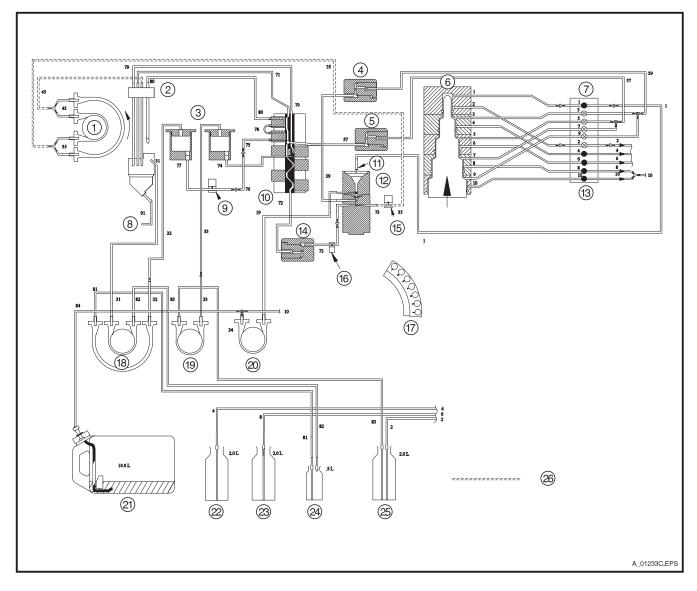
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- 1 EIC Drain
- 2 Electrolyte Drain
- 3 Fluid Dampers
- 4 Flow Mixer
- 5 Flow Mixer
- 6 Ratio Pump
- 7 Valve-E
- 8 Drain

- 9 Alkaline Buffer Solenoid Valve
- 10 Flow Cell
- 11 Flow Cell Solenoid Valve
- 12 EIC
- 13 EIC Drain Solenoid Valve
- 14 Valve State: 2
- 15 Alkaline Buffer
- 16 Electrolyte Reference
- 17 EIC Wash
- 18 Sample Sector
- 19 Sample Probe
- 20 CRE
- 21 BUN
- 22 GLU 23 - CA
- 24 Wash (Common Diluent)
- 25 Electrolyte Buffer
- 26 CO₂ Acid
- 27 Electrolyte Reference 28 CO₂ Alkaline Buffer
- 29 Electrolyte Reference
- 30 Sample
- 31 Valve Closed
- 32 Valve Open

Figure 4-11. CX3 Sample and Reagent Flow (Step 3B)

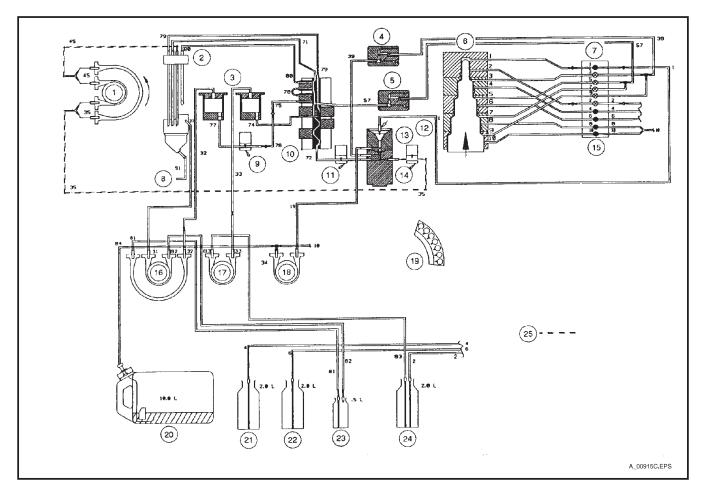


- 1 EIC Drain
- 2 Electrolyte Drain
- 3 Fluid Dampers
- 4 Flow Mixer
- 5 Flow Mixer 6 - Ratio Pump
- 7 Valve-E
- 8 Drain
- 9 Alkaline Buffer Solenoid Valve
- 10 Flow Cell
- 11 Sample Probe
- 12 EIC
- 13 Valve State: 2
- 14 Flow Mixer

- 15 EIC Drain Solenoid Valve
- 16 Flow Cell Solenoid Valve
- 17 Sample Sector
- 18 Alkaline Buffer
- 19 Electrolyte Reference
- 20 EIC Wash
- 21 Wash (Common Diluent)
- 22 Electrolyte Buffer
- 23 CO₂ Acid
- 24 CO₂ Alkaline Buffer
- 25 Electrolyte Reference
- 26 Wash

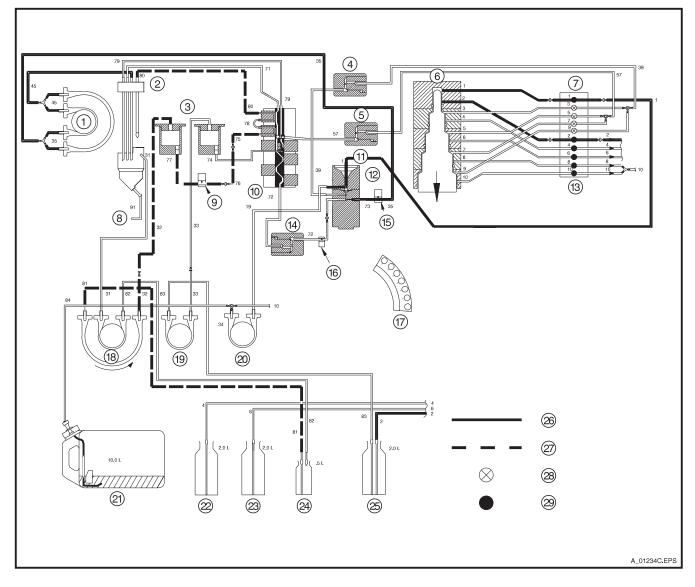
Figure 4-12. CX3 DELTA Sample and Reagent Flow (Step 4)

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- 1 EIC Drain
- 2 Electrolyte Drain
- 3 Fluid Dampers 4 - Flow Mixer
- 5 Flow Mixer
- 6 Ratio Pump
- 7 Valve-E
- 8 Drain
- 9 Alkaline Buffer Solenoid Valve
- 10 Flow Cell
- 11 Flow Cell Solenoid Valve
- 12 Sample Probe
- 13 EIC
- 14 EIC Drain Solenoid Valve
- 15 Valve State: 2
- 16 Alkaline Buffer 17 - Electrolyte Reference 18 - EIC Wash
- 19 Sample Sector
- 20 Wash (Common Diluent)
- 21 Electrolyte Buffer
- 22 CO₂ Acid
- 23 CO₂ Alkaline Buffer
- 24 Electrolyte Reference
- 25 Wash

Figure 4-13. CX3 Sample and Reagent Flow (Step 4)

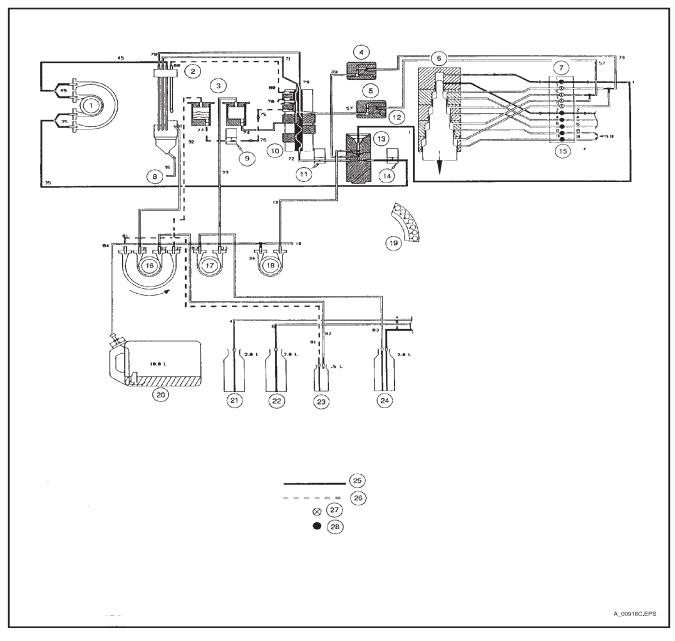


- 1 EIC Drain
- 2 Electrolyte Drain
- 3 Fluid Dampers
- 4 Flow Mixer
- 5 Flow Mixer
- 6 Ratio Pump
- 7 Valve-E 8 - Drain

- 9 Alkaline Buffer Solenoid Valve
- 10 Flow Cell
- 11 Sample Probe
- 12 EIC
- 13 Valve State: 4
- 14 Flow Mixer
- 15 EIC Drain Solenoid Valve
- 16 Flow Cell Solenoid Valve
- 17 Sample Sector
- 18 Alkaline Buffer 19 - Electrolyte Reference
- 20 EIC Wash
- 21 Wash (Common Diluent)
- 22 Electrolyte Buffer
- 23 CO₂ Acid
- 24 CO₂ Alkaline Buffer
- 25 Electrolyte Reference
- 26 Electrolyte Reference
- 27 Alkaline Buffer
- 28 Valve Closed 29 - Valve Open

Figure 4-14. CX3 DELTA Sample and Reagent Flow (Step 5)

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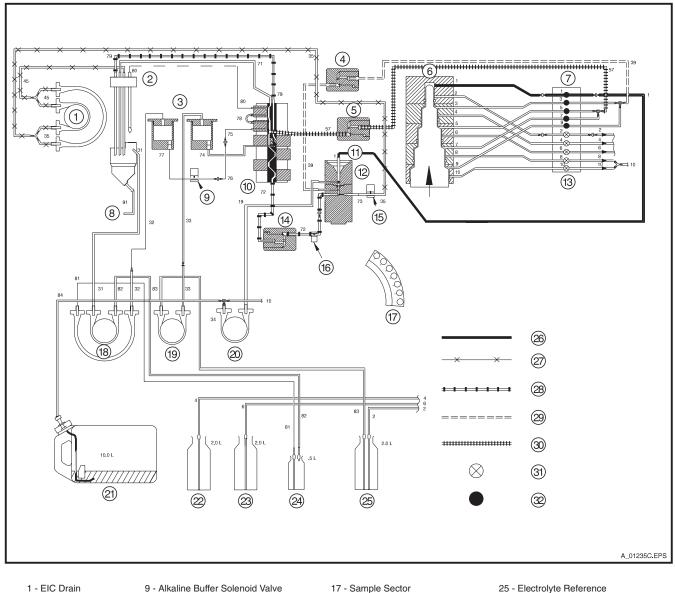


- 1 EIC Drain
- 2 Electrolyte Drain
- 3 Fluid Dampers
- 4 Flow Mixer
- 5 Flow Mixer
- 6 Ratio Pump
- 7 Valve-E
- 8 Drain

- 9 Alkaline Buffer Solenoid Valve
- 10 Flow Cell
- 11 Flow Cell Solenoid Valve
- 12 Sample Probe
- 13 EIC
- 14 EIC Drain Solenoid Valve
- 15 Valve State: 4
- 16 Alkaline Buffer

- 17 Electrolyte Reference
- 18 EIC Wash
- 19 Sample Sector
- 20 Wash (Common Diluent)
- 21 Electrolyte Buffer
- 22 CO₂ Acid
- 23 CO₂ Alkaline Buffer
- 24 Electrolyte Reference
- 25 Electrolyte Reference
- 26 Alkaline Buffer 27 Valve Closed
- 28 Valve Open

Figure 4-15. CX3 Sample and Reagent Flow (Step 5)



1 - EIC Drain

2 - Electrolyte Drain

3 - Fluid Dampers

4 - Flow Mixer

5 - Flow Mixer

6 - Ratio Pump

7 - Valve-E

8 - Drain

10 - Flow Cell

11 - Sample Probe

12 - EIC

13 - Valve State: 1

14 - Flow Mixer

15 - EIC Drain Solenoid Valve

16 - Flow Cell Solenoid Valve

17 - Sample Sector

18 - Alkaline Buffer

19 - Electrolyte Reference

20 - EIC Wash

21 - Wash (Common Diluent)

22 - Electrolyte Buffer

23 - CO₂ Acid

24 - CO₂ Alkaline Buffer

25 - Electrolyte Reference

26 - Electrolyte Reference

27 - Electrolyte Reference/Buffer Mixture

28 - Reference/Buffer/Acid Mixture

29 - Electrolyte Buffer

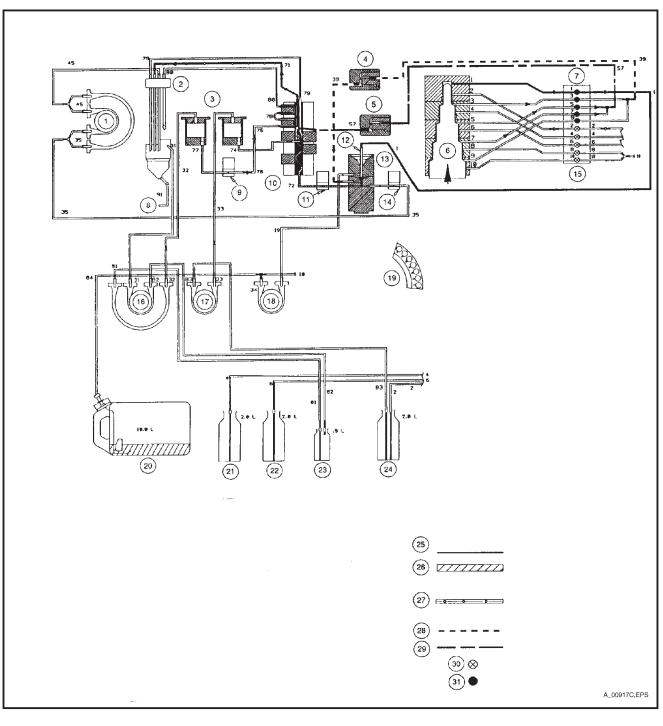
30 - CO₂ Acid Reagent

31 - Valve Closed

32 - Valve Open

Figure 4-16. CX3 DELTA Sample and Reagent Flow (Step 6)

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1 - EIC Drain

2 - Electrolyte Drain

3 - Fluid Dampers

4 - Flow Mixer

5 - Flow Mixer

6 - Ratio Pump

7 - Valve-E 8 - Drain

9 - Alkaline Buffer Solenoid Valve

10 - Flow Cell

11 - Flow Cell Solenoid Valve

12 - Sample Probe

13 - EIC

14 - EIC Drain Solenoid Valve

15 - Valve State: 1

16 - Alkaline Buffer

17 - Electrolyte Reference

18 - EIC Wash

19 - Sample Sector

20 - Wash (Common Diluent)

21 - Electrolyte Buffer

22 - CO₂ Acid

23 - CO₂ Alkaline Buffer

24 - Electrolyte Reference

25 - Electrolyte Reference

26 - Electrolyte Reference/Buffer Mixture 27 - Reference/Buffer/Acid Mixture

28 - Electrolyte Buffer

29 - CO2 Acid Reagent

30 - Valve Closed

31 - Valve Open

Figure 4-17. CX3 Sample and Reagent Flow (Step 6)

4.4.2 CX3 Reaction Cup Sample and Reagent Flow

This section describes sample and reagent flow for the reaction cup chemistries. It is important to remember that cup chemistries are concurrent with electrolyte measurements, even though the two types are presented separately for simplicity.

4.4.2.1 Reaction Cup Reagent Flow

The method of reagent handling is similar for glucose, BUN, total protein (or calcium), and creatinine. Exceptions are: individually numbered reagent lines, the valves used on pinch valve "C", and the number of peri-pump tubes required for each fill pump. Because total protein (or calcium) and creatinine reagents are not concentrated, they do not require dilution by the system. Therefore, they each have a single peri-pump tubing on their reagent fill pump. BUN and glucose, on the other hand, are concentrated reagents and require dilution with Wash Solution (common diluent) by the system. Thus, BUN and glucose require two peripump tubings per reagent fill pump: one for the concentrated reagent and one for the Wash Solution.

By step number, Figures 4-18 through 4-20 provide a description of the three basic operations of reagent fill, sip, and drain of, a reaction cup.

Using glucose as an example, the following steps occur:

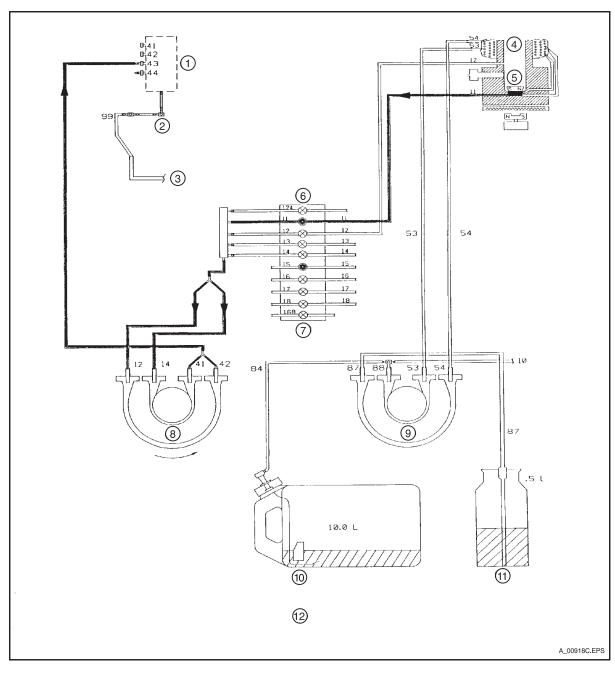
- C-valve number 11 opens and valve number 12 closes. The glucose/creatinine sip/drain peripump (number 1) turns on and all glucose reagent is drained from the cup.
- C-valve number 11 closes and valve number 12 opens. The fill peri-pump (number 7) turns on and fills the reaction cup. (The cup is slightly overfilled and the excess is sipped off in the next step.)

NOTE

The glucose peri-pump has dual delivery tubing. The green tubing delivers the concentrated reagent to the reaction cup. The red tubing delivers Wash Solution for diluting purposes.

3. C-valve number 11 remains closed and valve number 12 remains open. The sip/drain peripump (number 1) turns on and the excess reagent is sipped from the reaction cup. A precise volume of reagent remains in the cup for each sample measurement.

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1 - Drain Manifold

4 - GLU

7 - Valve State: 6

10 - Wash (Common Diluent)

2 - Drain 3 - Drain Tube to CX4CE 5 - Stirrer 6 - Valve-C 8 - Drain, Sip, GLU, CREA 9 - GLU Fill

12 - Step1: Reaction Cup Reagent Drain Sequence

Figure 4-18. Reagent Drain

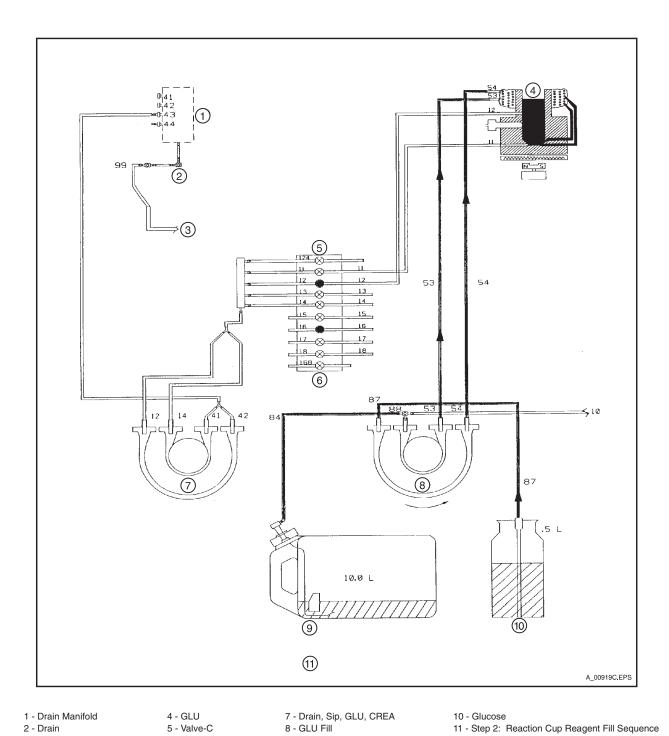


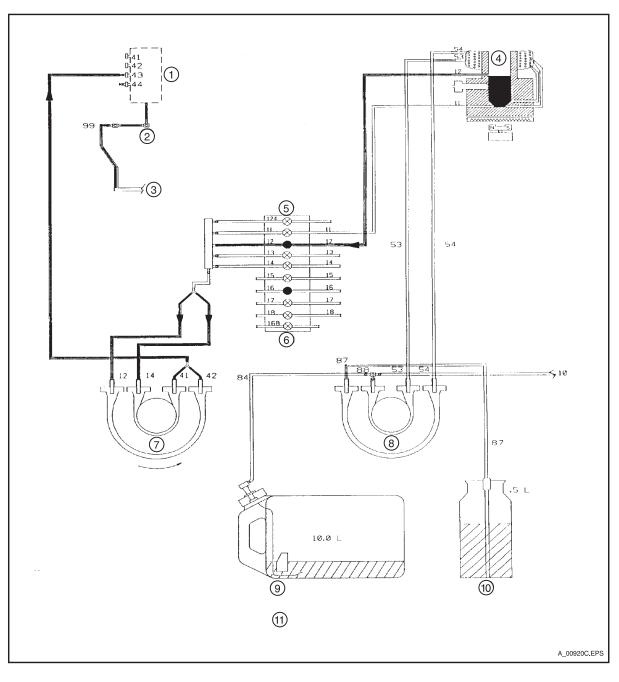
Figure 4-19. Reagent Fill

3 - Drain Tube to CX4CE

6 - Valve State: 7

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9 - Wash (Common Diluent)



1 - Drain Manifold

4 - GLU

7 - Drain, Sip, GLU, CREA 8 - GLU Fill

10 - Glucose

2 - Drain 3 - Drain Tube to CX4CE 5 - Valve-C 6 - Valve State: 7

9 - Wash (Common Diluent)

11 - Step 3: Reaction Cup Reagent Sip Sequence

Figure 4-20. Reagent Sip

4.4.2.2 Reaction Cup Sample Handling

- 1. At the appropriate scheduled interval, the sample wheel rotates and aligns the designated sector into position for aspiration. The sample crane moves the pickup probe over sample tube or cup. During a brief hesitation before the probe enters the cup, a 3 µL air slug is drawn into the probe to displace the ISE Electrolyte Reference solution that is resident in the pickup probe. The probe enters the sample and aspirates 7 mL of scrub sample. The probe retracts form the sample, and in the process aspirates an additional 4 mL air slug. The probe re-enters the sample and the appropriate volume of sample is drawn into the probe by the top cylinder of the ratio pump. Sample size is determined by the requirements of the chemistries requested.
- The sample crane rises, first rotates to the EIC where the sample probe is washed externally, then rotates to the reaction cups in the order BUN, total protein (or calcium), glucose, and creatinine.

NOTE

Sensitivity to interference determines the order of analytes. BUN is first because it is the most sensitive to other reagent carryover; and creatinine is last because it presents the greatest possibility of interference to other cup chemistries.

- At each reaction cup, the probe moves down and the ratio pump injects the proper amount of sample. The probe stops at every station, whether or not programming has requested the analyte.
- 4. All reaction cups are filled with the proper amount of the appropriate reagent. (Glucose measurement is based on an oxygen-rate method. Because the reagent deteriorates by exposure to surrounding air, it is renewed periodically.)
- 5. Reagent temperature is regulated by a reagent preheater and a reaction cup heater.
- The sample-reagent mixture in each reaction cup is mixed thoroughly by a magnetic stirrer that is driven by a stirrer motor under the cup.
- Each reaction cup module sends a sample signal to the appropriate analog board for processing.
- 8. Peri-pumps for each reaction cup drain the cup.
- Using the fill/sip cycles, the related peri-pumps fill all reaction cups with reagent. The reaction cups are ready for the next sample measurement sequence.

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- 1 EIC Drain
- 2 Electrolyte Drain
- 3 CO₂ Alkaline Buffer Fluid Damper
- 4 Electrolyte Reference Fluid Damper
- 5 Flow Mixer
- 6 Flow Mixer
- 7 Ratio Pump
- 8 Valve -E
- 9 Gray Tubes
- 10 Max./Min.
- 11 Max./Min.
- 12 Drain Manifold
- 13 Alkaline Buffer Solenoid Valve
- 14 Flow Cell
- 15 Flow Mixer
- 16 EIC
- 17 EIC Drain Solenoid Valve
- 18 Sample Probe
- 19 Drain Tube to CX4
- 20 Valve -C
- 21 Flow Cell Solenoid Valve
- 22 Red = Reagent
- 23 BUN
- 24 Stirrer
- 25 Red = Reagent
- 26 GLU
- 27 Stirrer
- 28 CREA 29 - Stirrer
- 30 CA/TP
- 31 Stirrer
- 32 Gray Tubes
- 33 Drain, Sip, GLU, CREA 34 - Gray Tubes
- 35 Drain, Sip, BUN, CA/TP
- 36 Red Tube
- 37 Alkaline Buffer 38 - Gray Tube
- 38 Gray Tube 39 - Red Tube
- 40 Electrolyte Reference
- 41 EIC Wash
- 42 Gray Tube
- 43 Green Tube
- 44 BUN Fill
- 45 Red Tube 46 - GLU Fill
- 47 Green Tube
- 48 Red Tube
- 49 CA/TP Fill 50 - Red Tube
- 51 CREA Fill
- 52 Red Tube
- 53 Wash (Common Diluent)
- 54 Electrolyte Buffer
- 55 CO₂ Acid
- 56 Electrolyte Reference
- $57 CO_2$ Alkaline Buffer
- 58 BUN
- 59 Glucose
- 60 Calcium/Total Protein
- 61 Creatinine

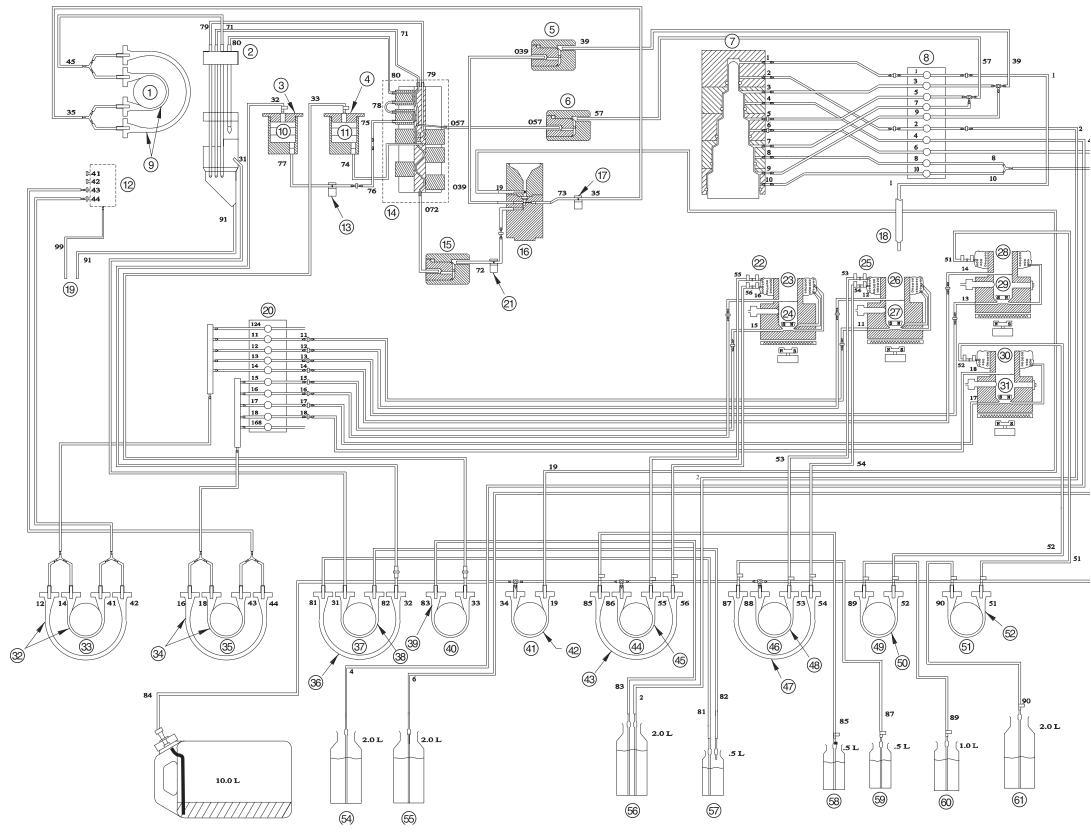


Figure 4-21. CX3 DELTA System Reagent Flow Diagram

- 1 EIC Drain
- 2 Electrolyte Drain
- 3 CO₂ Alkaline Buffer Fluid Damper
- 4 Electrolyte Reference Fluid Damper
- 5 Flow Mixer
- 6 Flow Mixer
- 7 Ratio Pump
- 8 Valve -E
- 9 Gray Tubes
- 10 Drain Manifold
- 11 Drain Tube to CX4
- 12 Alkaline Buffer Solenoid Valve
- 13 Flow Cell
- 14 Flow Cell Solenoid Valve
- 15 EIC
- 16 EIC Drain Solenoid Valve
- 17 Red = Reagent
- 18 Red = Reagent
- 19 Sample Probe
- 20 BUN
- 21 GLU
- 22 CREA
- 23 CA
- 24 Gray Tubes
- 25 Drain, Sip, GLU, CREA
- 26 Gray Tubes
- 27 Drain, Sip, BUN, CA
- 28 Red Tube
- 29 Alkaline Buffer
- 30 Gray Tube
- 31 Red Tube
- 32 Electrolyte Reference
- 33 EIC Wash 34 - Gray Tube
- 35 Green Tube
- 36 BUN Fill 37 - Red Tube
- 38 GLU Fill
- 39 Green Tube
- 40 Red Tube
- 41 CA Fill 42 - Red Tube
- 43 CREA Fill
- 44 Red Tube

53 - Creatinine

- 45 Wash (Common Diluent)
- 46 Electrolyte Buffer
- 47 CO₂ Acid 48 - Electrolyte Reference 49 - CO₂ Alkaline Buffer 50 - BUN 51 - Glucose 52 - Calcium

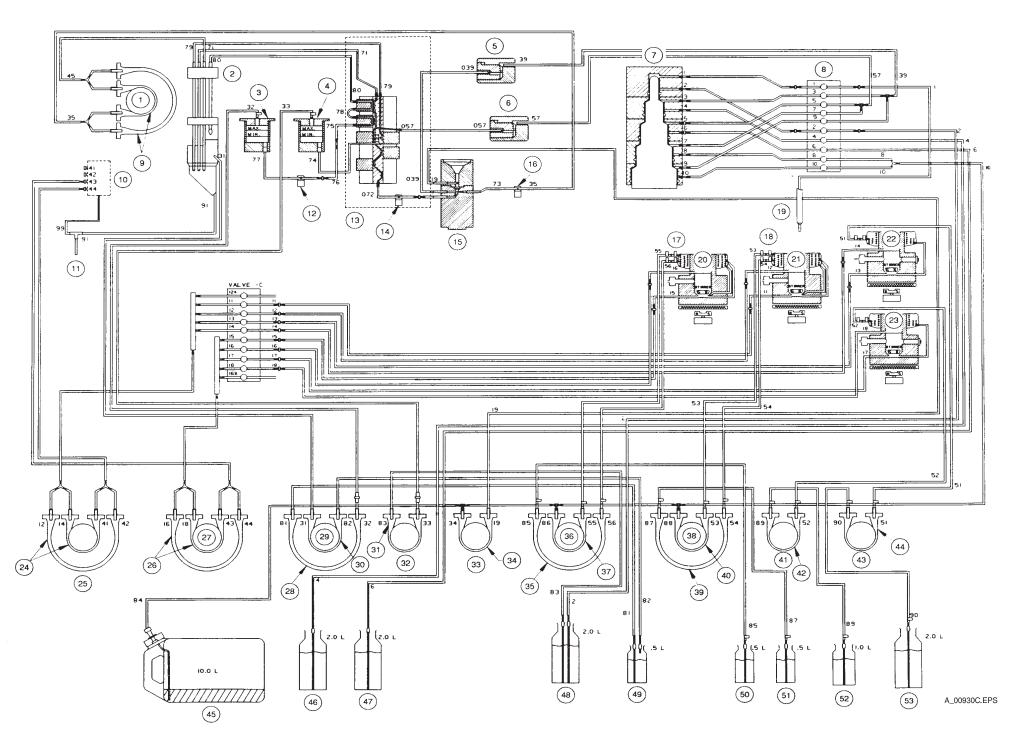


Figure 4-22. CX3 Systems Reagent Flow Diagram

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4.5 CX3 PRINCIPLES OF MEASUREMENT

4.5.1 Electrolytes

In the determination of electrolytes, a precise volume of sample (62 μ L) is mixed with a buffered solution. High molar-strength metal ion buffer is employed to establish a constant ionic strength. This serves to set a constant activity coefficient for each electrode.

Once a sample is aspirated and diluted, it is sent through the flow cell, where it comes in contact with the measuring electrodes. The concentration signals originating at the electrodes are converted by analog amplifiers and presented to the microprocessor, where they are scaled and converted to actual concentration values.

Each measurement cycle consists of two separate readings: sample and ISE Electrolyte Reference solution. The diluted sample is first measured by the electrodes in the flow cell. Immediately following this measurement, a precise aliquot of ISE Electrolyte Reference solution is also diluted and delivered to the flow cell for measurement. The reference solution readings provide for known concentrations of 140 mmol/L sodium, 4 mmol/L potassium, 100 mmol/L chloride, 10 mmol/L CO₂, and 8 mg/dL Calcium. These are subtracted from the sample readings to adjust for drift in the electrodes and electronics. Each electrode measurement is discussed in the following paragraphs. (Refer to the Chemistry Information Manual for more detailed information.)

4.5.1.1 Sodium Electrode Measurement

The sodium electrode and associated circuit elements, together with the reference electrode, determine the activity of ions in the unknown solution. Since the sodium ions present in biological fluids bear a direct relationship to the actual concentration of sodium in solution, the ion-selective electrode can effectively measure the quantity.

The Beckman sodium electrode uses a solid membrane produced from aluminum silicate (LAS) glass. When sample contacts the measuring electrode, sodium ions undergo an ion exchange in the hydrated outer layer of the LAS glass electrode. As the ion exchange takes place a change in potential is established that follows the Nernst Equation (Figure 4-23). This allows calculation of the sodium ion concentration in solution. Under ideal conditions, the electrode imparts a selectivity of 300 to 1 over potassium ions. The electrode is insensitive to hydrogen ions in solutions buffered from pH 6 to 10.

$$E = E^{\circ} + \frac{RT}{nF}I_n a_i$$

E° = Standard potential of electrode

R = Gas constant
T = Temperature
n = Charge of ion
F = Faraday's constant
a_i = Activity of the ion

Figure 4-23. Nernst Equation

4.5.1.2 Potassium Electrode Measurement

Similar to the sodium electrode, the potassium electrode is also an ion-selective device. A valinomycin membrane located at the face of the electrode contains cavities nearly equal to the diameter of the potassium ion. When the potassium ions fill the membrane cavities, the resulting voltage change follows the Nernst Equation. In conjunction with the sodium reference electrode, the potassium electrode then determines the activity of potassium present in the membrane and converts it to concentration. Under ideal conditions, the electrode has a selectivity of 1000 to 1 over sodium. The valinomycin membrane is insensitive to hydrogen ions in solutions buffered from pH 3 to 9.

4.5.1.3 Chloride Electrode Measurement

The chloride ion-selective electrode is a two-phase Ag/AgCl type. An equilibrium is developed at the surface of the electrode. Equilibrium is dependent upon the solubility product (Ksp) of the silver and chloride ions in the solution according to the following reaction:.

AgCl
$$\longrightarrow$$
 Ag⁺(aq) + Cl⁻(aq)

$$K_{sp} = \frac{[Ag^+][Cl^-]}{[AgCl]}$$

When chloride ions are introduced into the system, the Ksp is disrupted as Ag⁺ ions from the AgCl phase of the electrode move into the sample/buffer solution. The silver metal phase of the chloride electrode senses changes in potential that are due to the Ag⁺ ions of the AgCl phase. The Ag⁺ metal phase of the chloride electrode thus responds indirectly to the chloride ion activity in the sample.

4.5.1.4 Calcium Electrode Measurement

The ISE Electrolyte Buffer acts as a metal ion buffer. Sample diluted with buffer keeps the mole fraction of free calcium constant. When the sample buffer mixture contacts the electrode, calcium ions complex with the ionophore at the electrode surface. Changes in potential (voltage) develop at the electrode surface as the reaction occurs. These changes in potential are referenced to a sodium-reference electrode to compensate for small temperature and electrical noise variation by common-mode rejection analysis. The "referenced signal" is used in calculating the analyte concentrations based on the Nernst equation.

 $E_{\text{(at calcium electrode)}} = Constant + (Slope)(Log [Ca^{++}])$

4.5.1.5 Carbon Dioxide Electrode Measurement

The CO_2 electrodes (measurement and reference) are actually modified pH electrodes covered by a silicone rubber membrane. The principle of carbon dioxide measurement is based on the rate of pH change as CO_2 is liberated from a sample. When diluted sample is delivered through the flow cell, a precise volume of acid reagent is mixed to this sample stream. The mixture of the acid with sample converts all forms of carbon dioxide into CO_2 gas according to the following reaction:

$$CO_2 + H_2CO_3 + HCO_3^- + CO_3^= + R-NHCOO^- + Acid \rightarrow CO_2(g) + H_2O$$

A proportional amount of the liberated carbon dioxide gas passes through the silicone rubber membrane, thereby lowering the pH of an alkaline buffer solution located between the membrane and the face of the electrode. The rate of the pH change is directly proportional to the carbon dioxide concentration in the sample. The rate signal is compared with an identical electrode used as a reference, and the difference is converted into the appropriate concentration units.

4.5.2 Glucose

Glucose determination in the CX3 uses the oxygen rate method developed by Beckman. A Beckman Oxygen Electrode measures the rate of change in oxygen consumption when a sample is injected into an enzyme reagent solution.

A 10 μ L sample is injected into an enzyme reagent solution causing the glucose to undergo change according to the following reaction:

$$\begin{array}{c} \text{glucose} \\ \beta \text{ - D - glu + O}_2 \text{ + H}_2\text{O} \xrightarrow{\text{oxidase}} \\ \text{gluconic acid + H}_2\text{O + 4e}^- \end{array}$$

In the reaction, oxygen is consumed at the same rate as glucose reacts to form gluconic acid. A typical oxygen depletion versus time curve is shown in Figure 4-24. The rate of oxygen consumption versus time is shown in Figure 4-25.

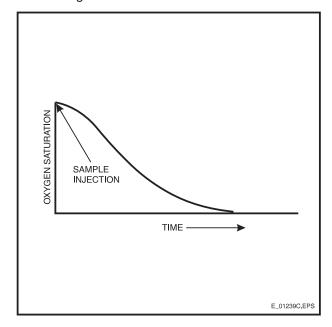


Figure 4-24. Oxygen Depletion Versus Time

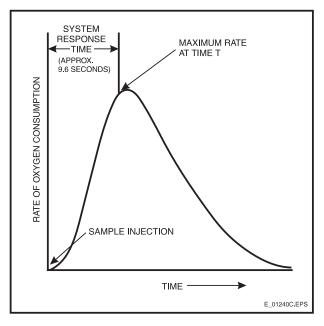


Figure 4-25. Rate of Oxygen Consumption Versus Time

At all times during the reaction, the rate of oxygen consumption is directly proportional to the concentration of glucose present in the reaction cup. The observed rate, attained after a brief interval required for reagent mixing and system response, has been shown to be a direct measure of the concentration of glucose originally present in the sample at the time of sample injection. Because oxygen consumption rather than peroxide formation is

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measured, the only requirement for peroxide is that it must be destroyed by a path not leading back to oxygen. The addition of ethanol to the reagent causes peroxide to be destroyed by catalase without yielding oxygen, according to the following reaction:

$$H_2O_2$$
 + Ethanol $\xrightarrow{\text{catalase}}$ Acetaldehyde + H_2O

To ensure destruction of the peroxide, iodide and molybdate are added to the enzyme reagent, causing the following reaction:

$$H_2O_2 + 2H^+ + 2I^- \xrightarrow{molybdate} I_2 + H_2O$$

This reaction is effective even after catalase activity has diminished with storage.

4.5.3 Urea Nitrogen

The CX3 determines urea nitrogen by means of the enzymatic conductivity rate method employing a Beckman Conductivity Electrode. When a 10 μ L of sample is injected into a precise volume of urease reagent in a reaction cup the urea in the serum undergoes changes according to the following reaction equation:

$$H_2N - C - NH_2 + 3H_2O \xrightarrow{urease} 2NH_4^+ + HCO_3^- + OH^-$$

The result of the reaction equation is the conversion of the non-ionic urea to one which is ionic (ammonium carbonate). During the reaction, electronic circuits determine the timed rate of increase of solution conductivity, which is directly proportional to the concentration of urea then present in the reaction cup. The observed rate, measured 11.5 seconds after injection of control, standard, or sample has been shown to be a direct measure of the concentration of urea originally present in the sample at the time of introduction. The system measures this rate at the "T" (Figure 4-26) and permits the resultant value to be scaled, providing a number corresponding to the urea concentration in milligrams of urea nitrogen per 100 milliliters (mg/dL).

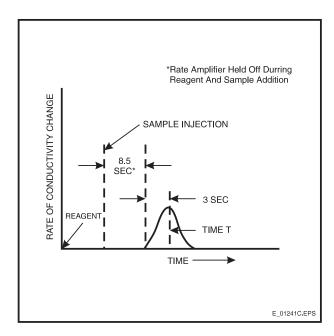


Figure 4-26. Urea Nitrogen Rate of Conductivity
Change Versus Time

Figure 4-27 illustrates the conductivity change during the urea hydrolysis. A typical curve for the analysis begins with the relative conductivity near zero as the reaction cup is standing empty. When the reaction cup is filled with urease solution, the conductivity rises to about 30% of full scale and holds steady until sample is injected. When sample is injected, there is a large and instantaneous jump in conductivity of serum relative to the urease solution. The conductivity then rises as the reaction proceeds, following roughly the typical kinetics for urease.

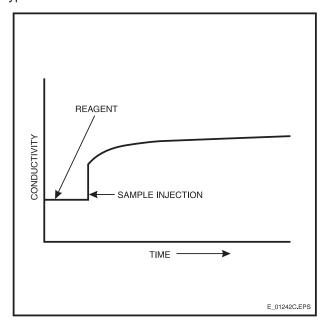


Figure 4-27. Urea Conductivity Versus Time

4.5.4 Creatinine

The CX3 determines creatinine by measuring the change in absorbance of an alkaline picrate solution following the addition of sample. This method is also know as the Jaffe rate method. The bichromatic detection system of the CX3 consists of a light source, a beam splitter, a 520 nm filter (sample detector), a 560 nm filter (reference detector), and two photodetectors. When a sample (30 μL serum/plasma, 10 μL urine) is introduced into the reaction cup containing a creatinine reagent solution, absorbance readings are taken simultaneously at both 520 nm and 560 nm. The change of absorbance is used for calculation purposes. Creatinine from the sample combines with the reagent to produce a red color complex (Figure 4-28).

Figure 4-28. Creatinine Color Development Reaction

The rate of colored creatinine-alkaline picrate complex formation is followed at 520 nm and 560 nm for 25.6 seconds after sample introduction. A typical creatinine absorbance versus time curve is shown in Figure 4-29.

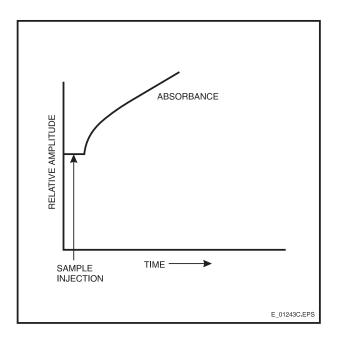


Figure 4-29. Typical Creatinine Absorbance Versus Time

The observed rate measurement at 25.6 seconds after sample introduction has been shown to be a direct measurement of the concentration of the creatinine in the sample.

4.5.5 Calcium (Cup)

The CX3 determines total calcium by means of a bichromatic end-point methodology. A 10 μ L sample is introduced into a reaction cup containing Arsenazo III Calcium Reagent. The CX3 measures the change in Arsenazo III Calcium Reagent following sample addition. The optical detection system consists of a light source, a beam splitter, a 650 nm filter and a 700 nm filter (sample detector), and two photodetectors. When a sample is introduced into the reaction cup containing the Arsenazo III reagent solution, calcium from the sample combines with the reagent to form a bluish-purple complex (Figure 4-30)

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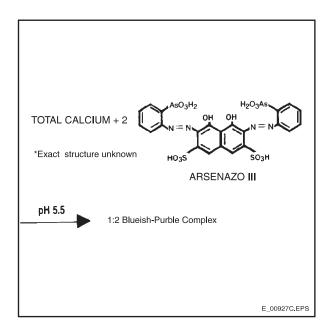


Figure 4-30. Calcium Reaction Complex

The absorbance of the colored calcium-Arsenazo III complex is measured at both 650 nm and 700 nm. The bichromatic absorbance change is used for calculations of calcium concentration in the sample. The final absorbance reading is taken 21 seconds after sample introduction. A typical calcium absorbance versus time curve is shown in Figure 4-31.

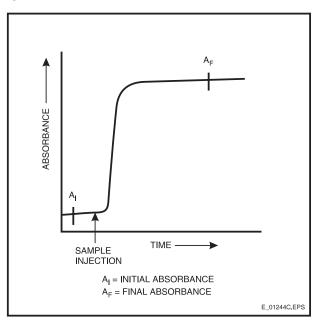


Figure 4-31. Typical Calcium Absorbance Versus Time

The differential absorbance, corrected for the reagent blank by the system electronics, is directly proportional to the calcium concentration in the sample.

4.5.6 Total Protein

The CX3 DELTA total protein chemistry determines total protein by means of the Biuret reaction-rate method. A 10 μ L serum/plasma sample (80 μ L CSF) is introduced into the alkaline copper reagent in a reaction cup. The CX3 measures the change in absorbance in an alkaline copper solution following the sample addition. The optical detection system consists of a light source, a 545 nm interference filter, and a photodetector. When a sample is introduced into the reaction cup containing reagent, absorbance readings are taken at 545 nm. The change of absorbance is used for calculation purposes. Peptide bonds from the proteins in the sample combine with the reagent to produce a dark blue-colored chelate (Figure 4-32).

NOTE

Urine total protein is not validated by BECKMAN for this sample type. If the operator chooses to perform a urine total protein, the sample should be pretreated in accordance with standard laboratory practice, and selected as a CSF sample type.

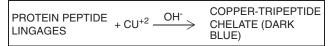


Figure 4-32. Total Protein Biuret Color-Development Reaction

The rate of colored peptide-copper chelate formation is followed at 545 nm for 11 seconds after sample introduction. A typical total protein absorbance versus time curve and the rate of color formation are shown in Figure 4-33.

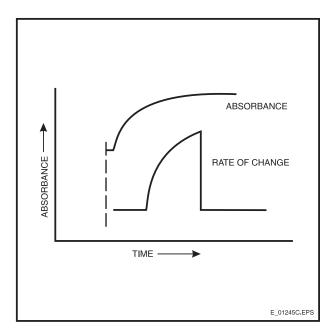


Figure 4-33. Typical Biuret Absorbances Versus
Time and Rate of Chelate Formation

The observed rate measurement at 11 seconds after sample introduction has been shown to be a direct measure of the concentration of total protein in the sample.

4.5.7 CX3 Analyte Signal Processing

Sensors, electrodes, and detectors are found in the electrolyte flow cell and chemistry reaction cups. The signals from the sensors, detectors and electrolytes are first sent to the respective analog circuit board where the signal is amplified and fed through an output circuit on the analog-to-digital conversion circuitry, where the analog signals are converted to digital form for entry into the system microcomputer.

During the sample measurement process in the CX3, each device in the flow cell or reaction cups generates an analog voltage that represents a concentration of a given analyte in the sample. The signal processing sequence that is shown in Figure 4-34 is similar in principle to that which was described for photometric measurements.

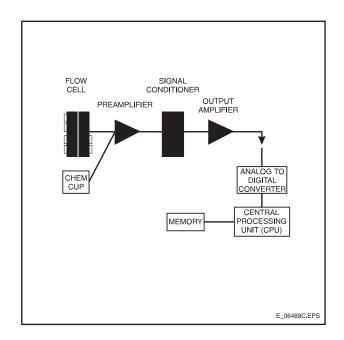


Figure 4-34. CX3 Signal Block Diagram

1. Analog Board

The signals originating from the flow cell are sent to the analog board where the electrode signals are conditioned prior to being directed to the ADC board. The analog board contains the necessary circuitry, which includes the following:

- (a) Pre-amplifier Circuits used to transform the high electrode impedance signals to very low values.
- (b) Differential Amplifiers subtract a reference voltage signal from each measuring electrode signal, as well as amplifying the resultant signal by a specific gain factor.
- (c) Multiplexers receive each signal from the differential amplifiers and, under microprocessor control, present four independent analog signals to the output amplifiers.
- (d) Output Buffer Amplifiers There are four output buffer amplifiers, one for each of the four analog signals, which are used to amplify each signal by a final gain factor prior to the ADC conversion process.

2. ADC Board

The electrode signals conditioned by the analog board are received by the ADC board where the analog-to-digital conversion process occurs. The four analog signals are selected individually for conversion by means of another multiplexer circuit. The main CPU receives and sends this data to the system console.

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4.6 CX3 MODULE CALIBRATION THEORY

Calibration of the ion-selective electrodes is similar in principle to that of the first order rate and endpoint chemistries in that the relationship between analyte concentration (sodium, potassium, chloride, CO₂ or Calcium ISE) to electrode potential is established. As opposed to a strict linear relationship between electrode response and concentration, the relationship is a logarithmic function that is defined by the Nernst Equation (Refer to Section 4.5 for details on ion-selective electrode theory). Appropriate factors, which are derived from the calibration curve, are used to calculate the final concentration results of unknown samples.

The CX3 utilizes a three level calibrator for all chemistries except total protein. However, some chemistries do not contain analyte in all 3 levels. When calibration begins, the system takes a sample from calibrator level 1 and injects the required calibration sample volume into designated positions. The resulting digital values (ADC numbers) are stored in the microprocessor as the first data points. The system then reruns the chemistries using another sample from calibrator level 1. After analysis of calibrator level 1 has completed, then samples from calibrator level 2 are assayed; after calibrator level 3 are assayed.

Total protein calibrators consist of 2 levels and follow the same calibration process described in the previous paragraph.

4.6.1 Calibration Error Detection

The analog signals generated by the calibrator measurements are converted to digital form. The resulting ADC values are compared to the preprogrammed back-to-back, span and range limits to determine the calibration acceptability.

4.6.1.1 Back-to-Back Test for Precision

Two replicates (minimum) are assayed for each calibrator level. The system microprocessor compares ADC values derived from the first two replicates. If the difference between the two ADC numbers is within limits, the system accepts the average of the two ADC values. If the difference between the first and second ADC numbers exceeds the limit, the first ADC is discarded and a third determination is made using the same calibrator level. If the second and third ADC values are within limits, then the average of these two values is accepted as a calibration set point. The system assays a maximum of four replicates providing values for three comparisons. If the values are outside the limits, then an ERR is printed instead of a

calibration set point value. If calibration fails, a "Failed Calibration Report" prints at the bottom of the completed calibration report, providing analyte, calibration level, and failure condition. The exception is the back-to-back calibrator check for CO₂. The calculation is based on a relative percentage. The formula for the calculation is the following:

$$\frac{(\text{CO}_2 \text{ D1 ADC}) - (\text{CO}_2 \text{ D2 ADC})}{\frac{\text{Reference 1} + \text{Reference 2}}{2}} * 100 < 5\%$$

	for the first injection of calibrator.
CO ₂ D2 ADC	The sample-reference ADC for the second injection of calibrator.
Reference 1	The difference between the ADC's for the first injection of calibrator.
Reference 2	The difference between the ADC's for the second injection

of calibrator.

The sample-reference ADC

4.6.1.2 Range Test for Accuracy

CO₂ D1 ADC

This test determines if the chemistry value set points fall within the acceptable range of values for that chemistry. If during calibration, a particular chemistry yields ADC numbers which exceed maximum or minimum limits, the calibration is not accepted and an ERR is printed instead of a calibration set point value. If calibration fails, a "Failed Calibration Report" prints at the bottom of the completed calibration report, listing the analyte, calibration level, and failure condition. A chemistry which fails the range test has ADC values exceeding an acceptable range of measurements, or in the case of BUN may indicate insufficient reagent strength.

4.6.1.3 Span Test for Measurement Sensitivity

The system compares the average ADC values for each set point of calibrators. The ADC numbers are the average ADC values from the back-to-back comparison described in Paragraph 4.6.1.1. The difference between the average ADC of calibrator level 1 and the average ADC of calibrator level 2, or calibrator level 2 and calibrator level 3 must be greater than the minimum pre-programmed acceptance span value for that particular chemistry. If the difference does not exceed minimal acceptable span value,

subsequent chemistry measurements will probably not produce a representative change in signal for a corresponding change in solution concentration. If during calibration a chemistry fails the span test, an ERR is printed instead of a calibration set point value. If calibration fails, a "Failed Calibration Report" prints at the bottom of the completed calibration report, listing the analyte, calibration level, and failure condition. Also the numeric value of the span is printed at the bottom of the calibration printout.

4.6.2 ADC Numbers

If a chemistry fails any of the calibration limits described in the previous sections, a closer examination of the ADC numbers is warranted. A description of these ADC numbers for different chemistries follows:

4.6.2.1 Sodium, Potassium, Chloride and Calcium (ISE) Calibration ADC Numbers

During each electrolyte measurement, two distinct measurement cycles occur. The first cycle is a measurement of the actual calibrator diluted with Electrolyte Buffer Reagent. The ADC number corresponding to it is the Sample ADC. The second cycle is the Electrolyte Reference Reagent diluted with Electrolyte Buffer. The ADC number corresponding to it is the Reference ADC. The number that is actually used for back-to-back, range and span checks is the Sample Reference ADC. It represents the difference between the sample and electrolyte reference ADC numbers. There are also two additional ADC numbers for each analyte measurement. These are useful in determining the stability of a calibration reading. Each sample and electrolyte reference ADC printed is actually an average of four readings. The ADC difference between these readings is indicated by a Sample Deviation (difference in sample ADC's) and a Reference Deviation (difference in reference ADC's). The ADC difference must be less than 15 for Na, K and CI Samples and K Reference and less than 30 for Na and CI Reference or an erratic ADC error message will be generated. A summary of the preceding is below:

SMPL = Sample - reference ADC

REFERENCE

REFERENCE = Electrolyte reference ADC

SAMPLE = Sample ADC number

SMPL DEVIATION Difference between highest and lowest sample ADC

number

REF DEVIATION Difference between highest and lowest reference ADC

number

4.6.2.2 Carbon Dioxide Calibration ADC Numbers

The CO_2 measurement is a rate pH measurement. The same two measurement cycles apply to CO_2 as for sodium, potassium, chloride and calcium (ISE) measurements. However, the readings are slightly different. For the sample cycle, there are two readings, S_1 and S_2 . The S_1 reading is the initial reading by the CO_2 measuring electrode. The S_2 reading is the final rate reading by the CO_2 measuring electrode. R_1 is the initial electrolyte reference reading and R_2 is the final rate reading of the electrolyte reference and buffer solution. Therefore, a rate difference is determined between S_1 and S_2 , and R_1 and R_2 . The SMPL REFERENCE ADC on the printout is the number that is used to check back-to-back, range and span. It is derived in the following manner:

Sample

Reference = $(R_1 - R_2) - (S_1 - S_2)$

R₁ = Initial electrolyte reference reading

R₂ = Final rate reading of the electrolyte reference and buffer solution

S₁ = Initial reading by the CO₂ measuring electrode

 S_2 = Final rate reading by the CO_2 measuring electrode

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4.6.2.3 Glucose and Bun Calibration ADC Numbers

The calibrator ADC numbers for glucose and BUN calibration are represented by the RATE, INIT READ and FINAL READ. Rate represents the rate of change in ADC's during the reaction . INIT READ represents the conductance measured by the electrode when only reagent is present in the cup. FINAL READ is the conductance measured by the electrode after the reaction has taken place. The Rate ADC is the number that is used for checking back-to-back, range and span. Following is a summary of the glucose and BUN ADC numbers.

RATE = Reaction Rate ADC

INIT READ = Initial Conductance ADC

FINAL READ = Final Conductance ADC

4.6.2.4 Calcium (Cup) Calibration ADC Numbers

The calcium chemistry is an endpoint chemistry which uses and Arsenazo Dye and bichromatics for determinations. INIT READ, FINAL READ, and DELTA ABS describe the calcium ADC numbers during calibration. INIT READ is the absorbance of the reagent before sample injection. The INIT READ represents a difference in absorbance of the detectors at 650 and 700 nm wavelengths.

Calibrator is injected and an absorbance reading is taken again and it is represented by the ADC value labelled FINAL READ. It too is the difference is absorbance between 650 and 700 nm wavelengths. The DELTA ABS is the difference between the initial absorbance and the final absorbance ADC numbers. DELTA ABS is used to check back-to-back, range, and span. Following is a summary of the calcium ADC numbers.

INIT READ = Initial Absorbance ADC

FINAL READ = Final Absorbance ADC

DELTA ABS = Delta between Initial and Final

Absorbance ADC

4.6.2.5 Creatinine Calibration ADC Numbers

The creatinine chemistry utilizes a rate Jaffé reaction. An initial reading (INIT READ) is taken with only reagent in the cup. This reading is the difference in absorbance readings of detectors utilizing 520 and 560 nm wavelengths. Initial read is used to check cup cleanliness or carryover. If initial read is too high (out of range high), a DAC initialization error will occur resulting in calibration error or suppressed results.

Calibrator is injected into the reagent and the rate of absorbance change is determined at two different wavelengths. This rate reading is represented on the printout by the ADC value labelled RATE. This ADC number is used to check back-to-back, range, and span calibration parameters. Following is a summary of the creatinine ADC numbers.

INIT READ = Difference in absorbance

readings of detectors utilizing 520 and 560 nm wavelengths.

RATE = Rate of absorbance change

determined at two different

wavelengths.

4.6.2.6 Total Protein Calibration ADC Numbers

The total protein chemistry uses a timed-rate Biuret reaction measured by a detector at 545 nm. An initial reading (INIT READ) is taken with only reagent in the cup. Calibrator is injected into the reagent, the rate amplifier is turned on, the RATE is measured, then the rate amplifier is turned off. A FINAL READ is taken. The Rate ADC is the number that is used for checking back-to-back, range, and span. Following is a summary of the total protein ADC numbers:

RATE = Reaction Rate ADC

INIT READ = Initial Absorbance ADC

FINAL READ = Final Absorbance ADC

4.7 SPECTROPHOTOMETRIC PRINCIPLES OF MEASUREMENT OF THE CX4

Spectrophotometric methods are based on the principle that when a sample, such as patient serum, a control, or a calibrator, is mixed with one or more appropriate chemical reagents, a substance is produced that has the ability to absorb light at a specific wavelength. This substance is also referred to as a chromophore.

According to Beer's Law (Figure 4-35), the amount of light absorbed at the completion of the reaction (endpoint) is proportional to the concentration of the constituent being measured. The rate of formation of the chromophore, as indicated by the rate of change of the absorption of light, can also be selected as a means of measuring concentration.

			A = abc
where:	Α	=	absorbance of the sample
	а	=	absorptivity of the absorbing substance at the specific measuring wavelength
	b	=	cuvette pathlength
	С	=	concentration

Figure 4-35. Beer's Law

In utilizing spectrophotometric techniques, two different measurement modes can be implemented:

1. Endpoint Measurements

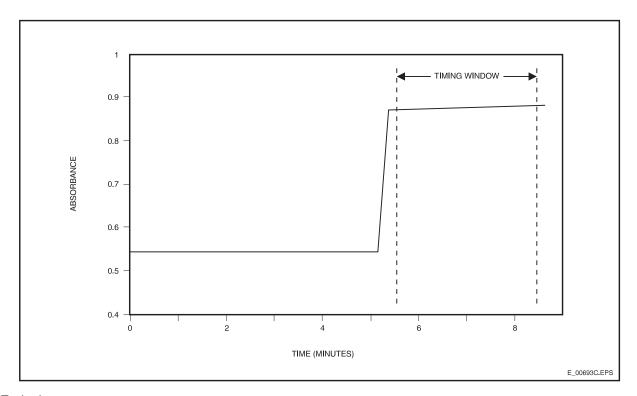
In endpoint reactions, the unknown concentration of the desired analyte in the sample can be determined by measuring the final absorbance change produced after the chemical reaction has reached completion (Figure 4-36A). At completion, the amount of chromophore that has developed or reduced is a function of the concentration of the unknown in the solution.

Endpoint chemistries are characterized by a large initial absorbance change following sample addition followed by a steady-state plateau indicating the completion of the reaction. For many chemistries, the final chromophore absorbance is compared with an initial baseline absorbance obtained on a cuvette containing reagent only (also referred to as a reagent blank). The difference between the final absorbance and the reagent blank is then used in the final calculation of concentration.

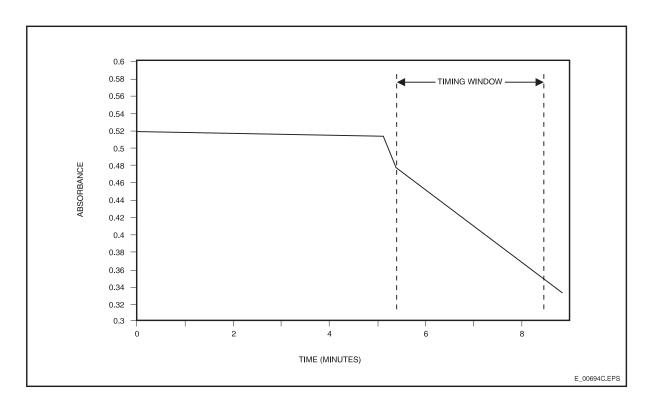
2. Rate Measurements

In rate chemistries, a series of measurements is recorded at specific time intervals while the reaction is progressing. The change in absorbance between successive measurements over a specified period of time is also a function of the concentration of the unknown analyte. Figure 4-36B illustrates a typical rate reaction absorbance curve as a function of time. Typically, absorbance readings are recorded during that time interval - the Timing Window (TW) - that exhibits the most linear portion of the reaction.

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A. Endpoint



B. RateFigure 4-36. Typical Endpoint and Rate Reaction Curves

4.7.1 Optical Light Path

In operation, photometric absorbance measurements of the solution in each cuvette occur during every analytical spin cycle. During this time the xenon lamp is synchronized to emit a flash of light as each cuvette passes through the optics station. (Refer to Paragraph 3.4.3.2, Photometer Assembly, for a description of the photometer unit.)

Figure 4-37 illustrates the optical path of the emitted light as it enters the monochromator assembly.

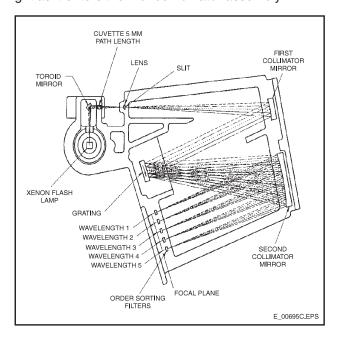


Figure 4-37. Optical Light Path

The resultant light passes through the cuvette and encounters a lens system which collimates the light and directs the resultant beams to a mirror. The mirror then reflects the light to a diffraction grating, which disperses the beam into its constituent wavelengths. Each wavelength band then reflects off a second mirror that directs the beams to the photo-diode array of detectors. Separate detectors are present to measure the following wavelengths: 340, 380, 410, 470, 520, 560, 600, 650, 670, and 700 nm.

4.7.2 Flash Correction

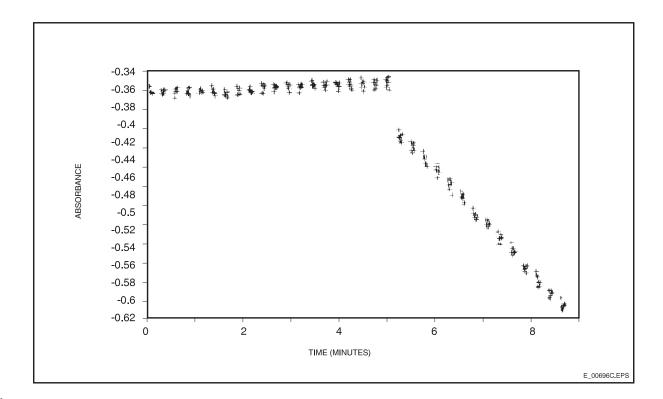
A potential source of error in the measurement of absorbance can be attributed to variations in the intensity of light each time the source lamp is flashed. Because the error contributed by flash variation is significant, it can affect precision and accuracy of the absorbance reading.

For this reason, the SYNCHRON System employs a correction technique that effectively eliminates the effect of the measurement errors caused by flash variation. The technique is based upon measurement of absorbances of the chromophore at secondary wavelengths in addition to the primary analysis wavelength. This is accomplished by the photometer assembly, which is capable of recording absorbances at up to five different wavelengths simultaneously.

The number and selection of secondary wavelengths will vary depending on the properties of the chromophore of interest. Fundamentally, however, any variation in intensity that occurs for a given flash also occurs in the same magnitude at the secondary wavelengths as well. This enables the variation to be characterized statistically through the calculation of a correction coefficient. From this, the appropriate absorptivity can be derived and applied to the observed absorbance for the chromophore at the primary analysis wavelength to yield an accurate flash-corrected absorbance value.

Figure 4-38 illustrates the effect of the flash correction technique for a chemistry employing a secondary wavelength correction. The top graph illustrates the variation of absorbance data points at both the primary analysis and at a secondary wavelength during each flash. The effect of the correction technique is evident in the bottom graph. It can be seen that the variation in the individual absorbance data points has been greatly reduced. This process ensures stable and accurate absorbance readings for use in the final calculation of results.

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Α

В

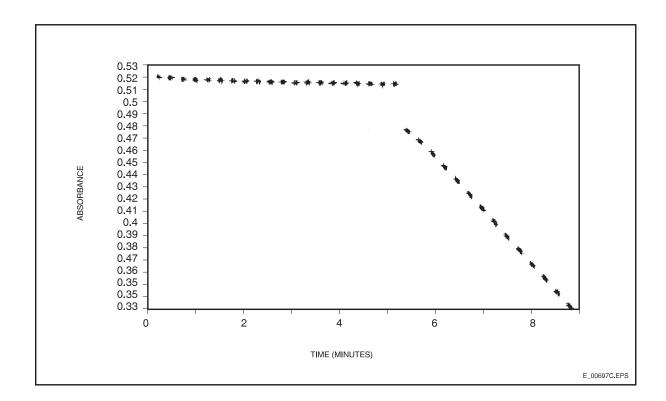


Figure 4-38. Flash-Corrected Absorbance Readings

4.7.3 Data Collection

Calculation of the final concentration of an unknown sample is derived from the absorbance measurements recorded for a given cuvette. The process of data collection and its subsequent calculation is presented in Figure 4-39.

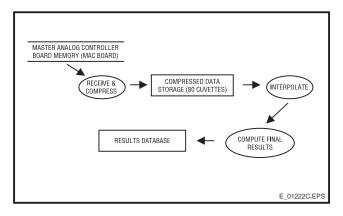


Figure 4-39. Data Collection Process

In routine operation, absorbance readings for up to five separate wavelengths can be taken during each analytical spin cycle as the cuvettes pass through the photometer station. During the time interval that the cuvette carousel is spun 10 times, a total of eight lamp flashes are utilized per cuvette. No readings are taken during the first or last spin. As previously discussed, each of the eight absorbance readings is corrected for flash variation.

The eight data points recorded from each spin cycle undergo a compression calculation routine that yields an average absorbance value that is then stored in memory. A linear regression of the data points is also performed in which a slope and average deviation about the regression line is determined. A check is done to flag any point that deviates too far from the regression line. If a data point is found to exceed predefined limits, the appropriate noise flag is identified and also stored in memory.

The number of successive spin cycles in which absorbance measurements are taken for a given chemistry reaction will depend on the particular measurement time interval defined for that chemistry. For example, a glucose reaction that is defined to have a measurement interval of 210 seconds (that is, the time from sample addition to completion of the reaction), will require absorbance measurements to be taken over a total of 13 successive analytical spin cycles (recall a spin cycle occurs every 16 seconds).

At the completion of the reaction, whether it be an endpoint or rate chemistry, a cubic interpolation of the successive mean absorbance values obtained from each spin cycle is performed. From the interpolation

routine, additional data points are derived which represent those points that occur during the interval that absorbance readings are not taken (that is, during the stationary service interval). The mathematical algorithms employed in the interpolation routine also provide an effective digital filtering technique to minimize undesirable electrical noise that could otherwise potentially affect the precision and accuracy of the recorded data.

Finally, following the interpolation routine, the resultant data points are used to calculate the final concentration. This is accomplished by selecting the data contained within the appropriate read window for a particular chemistry (Figure 4-40).

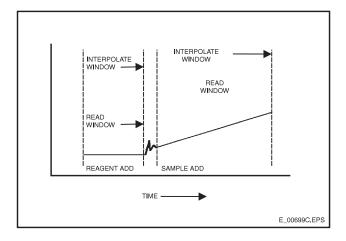


Figure 4-40. Measurement Read Window

For endpoint chemistries, results are calculated from the mean absorbance value; for rate chemistries, the mean slope (the rate of change of absorbance) is used in calculation of the final results.

4.7.4 Electronic Signal Processing

The sequence of the electronic signal processing is as follows:

1. Signal Conditioners

Signals from five of the photodetectors can be recorded simultaneously. Each of the five photodetector channels has a separate signal-conditioning circuit that is located on the ADC board. Each signal-conditioning circuit includes a log amplifier to boost the low-level signal derived from the photodetectors and an output circuit to provide an available signal for the multiplexer circuit.

2. Multiplexer

The multiplexer receives the signals from the signal-conditioning circuits and, under micro-

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processor control, presents them individually to the analog-to-digital converter.

3. Analog-to-Digital Converter (ADC)

The various analog signals (represented in millivolts) are converted to digital signals, which are subsequently used by the central processing unit (CPU) for calculation of final results.

The microprocessor coordinates activities between the ADC and multiplexer by signalling the ADC when an analog signal is available for conversion. Following conversion, the ADC informs the microprocessor that the digital value is available for data calculation.

4. Central Processing Unit (CPU)

The main central processing unit is a Z8001 microprocessor. The flash-corrected absorbance data is collected and stored in random access memory (RAM) located on the master analog controller board. The CPU receives and utilizes this data for calculation of final results, which are then sent to the system console.

4.8 CX4 MODULE CALIBRATION THEORY

To ensure that the values recovered from patient sample assays are both accurate and precise, the SYNCHRON CX System performs a calibration procedure for most chemistries. Included in this broad category are the endpoint and first order rate chemistries, drugs, and specific proteins. The zero-order rate chemistries include enzymes which are precalibrated at the factory and require no routine calibration.

The purpose of the calibration procedure is to determine the relationship between measured absorbances to known concentrations of these same analytes contained in calibrator solutions (e.g., CX Multicalibrator). Once this relationship is determined, the appropriate calibration factors can then be derived. These factors are then used to convert the measured absorbances or electrode potentials to final concentration results.

4.8.1 Zero-Order Chemistries

Zero-order rate enzyme chemistries (for example, ALT, AST, CK, GGT, LD-L, LD-P, AMY, ALP) are precalibrated at the factory and require no routine calibration. The final result is calculated using one of the following two equations depending on the blanking mode used for that particular reagent:

1. Nonblanked reagents

Reaction_{rate} * Factor = sample value

2. Blanked reagents

 $(Reaction_{rate} - Blank_{rate}) * Factor = sample value$

The factor is a fixed predetermined value for each chemistry. The factor is used to scale the result to match a reference reagent.

AST-, ALT-, and CK- require calibration using SYNCHRON Enzyme Validator (P/N 441350). Refer to Section 4.8.2.1 for the calibration formula.

4.8.2 Endpoint and First-Order Rate Chemistries

Calibration of endpoint and first-order rate chemistries involve the use of a single-level calibrator solution (e.g., CX Multicalibrator). Each analyte in the calibration solution has a known concentration value associated with it. With each new lot of calibrator solution, the values are transferred and stored in memory for later use in the calibration procedure. (Refer to Paragraph 6.3.5, Calibrator Diskettes, for details on loading calibrator data.)

For most chemistries the CX4 will set calibration based on four calibrator replicates. The instrument will determine and discard the highest and lowest of the four replicates. The remaining two values are called the usable calibrator replicates. Only the two usable replicates will be reported. The average value of the usable calibrator replicates is used to determine the calibration factor.

For some chemistries, calibration will be based on two calibrator replicates. No replicates will be discarded. The average value of the calibrator replicates is used to determine the calibration factor.

4.8.2.1 Calibration Formulas

There are four single point calibration formulas that follow the four reaction types: blanked end point (endpoint 2), nonblanked end point (endpoint 1), blanked rate (rate 2), nonblanked rate (rate 1). The calibration factor is determined by using one of the following equation sets where reaction and blank are from the usable replicates:

1. Blanked endpoint chemistries:

For high calibrator level:

```
\begin{aligned} &(\text{Reaction ABS} - \text{Blank ABS}) = \text{Delta ABS} \quad_{\text{rep 1}} \\ &(\text{Reaction ABS} - \text{Blank ABS}) = \text{Delta ABS} \quad_{\text{rep 2}} \\ &(\text{Delta ABS}_{\text{rep 1}} + \text{Delta ABS}_{\text{rep 2}}) \star 0.5 = \text{Delta ABS}_{\text{avg}}(\text{hi}) \end{aligned}
```

For low calibrator level:*

```
(\text{Reaction ABS} - \text{Blank ABS}) = \text{Delta ABS} \quad \text{rep 1} \\ (\text{Reaction ABS} - \text{Blank ABS}) = \text{Delta ABS} \quad \text{rep 2} \\ (\text{Delta ABS}_{\text{rep 1}} + \text{Delta ABS}_{\text{rep 2}}) \star 0.5 = \text{Delta ABS}_{\text{avg}}(\text{lo}) \\ \text{CAL FACTOR (Slope)} = \frac{\text{Cal Set Point (hi)} - \text{Cal Set Point (lo)}}{\text{Delta ABS}_{\text{avg}}(\text{hi})} - \text{Delta ABS}_{\text{avg}}(\text{lo}) \\ \text{OFFSET} = \text{Cal set point (hi)} - \text{Cal Factor} \quad \star \text{ Delta ABS}_{\text{avg}}(\text{hi}) \\ \text{Table ABS}_{\text{avg}}(\text{lo}) + \text{Table ABS}_{\text{avg}}(\text{lo}) + \text{Table ABS}_{\text{avg}}(\text{lo}) \\ \text{Table ABS}_{\text{avg}}(\text{lo}) + \text{Table ABS}_{\text{avg}}(\text{lo}) + \text{Table ABS}_{\text{avg}}(\text{lo}) + \text{Table ABS}_{\text{avg}}(\text{lo}) \\ \text{Table ABS}_{\text{avg}}(\text{lo}) + \text{Table ABS}_{\text{avg}}(\text{lo}) + \text{Table ABS}_{\text{avg}}(\text{lo})
```

<u>Sample</u> values are calculated by the following equation:

[(Reaction ABS -Blank ABS) * Cal Factor] + offset = sample value

* For single point calibrators, the low calibrator is a fixed zero point.

2. Nonblanked endpoint chemistries:

For high calibrator level:

```
\label{eq:Reaction ABS} \mbox{ Reaction ABS = Absorbance}_{\mbox{rep 1}} \mbox{ Reaction ABS = Absorbance}_{\mbox{rep 2}} \mbox{ } \\ \mbox{ (Absorbance}_{\mbox{rep 1}} + \mbox{ Absorbance}_{\mbox{rep 2}}) * 0.5 = \mbox{ Absorbance}_{\mbox{avg}}(\mbox{hi}) \mbox{ } \\ \mbox{ } \\ \mbox{ } \end{array}
```

For low calibrator level:*

```
\label{eq:Reaction ABS} \ = \ Absorbance_{rep\ 1} \ Reaction\ ABS = \ Absorbance_{rep\ 2} (Absorbance_{rep\ 1} + Absorbance_{rep\ 2}) * 0.5 = Absorbance_{avg}(lo)
```

* For single point calibrators, the low calibrator is a fixed zero point.

$$\begin{aligned} \text{CAL FACTOR (Slope)} &= \frac{\text{Cal Set Point (hi)} - \text{Cal Set Point (lo)}}{\text{Absorbance}_{avg}(\text{hi)} - \text{Absorbance}_{avg}(\text{lo)}} \\ \text{OFFSET} &= \text{Cal Set Point (hi)} - \text{[Cal Factor} \quad \star \text{Absorbance}_{avg}(\text{hi)]} \end{aligned}$$

<u>Sample</u> values are calculated by the following equation:

(Reaction ABS * Cal Factor) + offset = sample value

3. Blanked rate chemistries:

For high calibrator level:

```
(Reaction Rate —Blank Rate) = Delta Rate _{rep\ 1} (Reaction Rate —Blank Rate) = Delta Rate _{rep\ 2} (Delta Rate_{rep\ 1} + Delta Rate_{rep\ 2}) \star 0.5 = Delta Rate_{avg}(hi)
```

For low calibrator level:*

```
(Reaction Rate –Blank Rate) = Delta Rate _{rep\ 1}
(Reaction Rate –Blank Rate) = Delta Rate _{rep\ 2}
(Delta Rate_{rep\ 1} + Delta Rate_{rep\ 2}) \star 0.5 = Delta Rate_{avg}(lo)
```

* For single point calibrators, the low calibrator is a fixed zero point.

$${\sf CAL\ FACTOR\ (Slope)} = \frac{{\sf Cal\ Set\ Point\ (hi)} - {\sf Cal\ set\ point\ (lo)}}{{\sf Delta\ Rate}_{avg}({\sf hi)} - {\sf Delta\ Rate}_{avg}({\sf lo)} }$$

OFFSET = Cal Set Point (hi) -[Cal Factor * Delta Rate_{avg}(hi)]

<u>Sample</u> values are calculated by the following equation:

[(Reaction Rate -Blank Rate) * Cal Factor] + offset = sample value

4. Nonblanked rate chemistries:

For high calibrator level:

```
\begin{aligned} \text{Reaction Rate} &= \text{Rate}_{\text{rep 1}} \\ \text{Reaction Rate} &= \text{Rate}_{\text{rep 2}} \\ (\text{Rate}_{\text{rep 1}} + \text{Rate}_{\text{rep 2}}) \star 0.5 &= \text{Rate}_{\text{avg}}(\text{hi}) \end{aligned}
```

For low calibrator level:*

```
\begin{aligned} \text{Reaction Rate} &= \text{Rate}_{\text{rep 1}} \\ \text{Reaction Rate} &= \text{Rate}_{\text{rep 2}} \\ (\text{Rate}_{\text{rep 1}} + \text{Rate}_{\text{rep 2}}) \star 0.5 = \text{Rate}_{\text{avg}}(\text{lo}) \end{aligned}
```

* For single point calibrators, the low calibrator is a fixed zero point.

CAL FACTOR (Slope) =
$$\frac{\text{Cal Set Point (hi) - Cal set point (lo)}}{\text{Rate}_{avg}(\text{hi) - Rate}_{avg}(\text{lo)}}$$
OFFSET = Cal set point (hi) -{Cal Factor * Delta Rate}_{avg}(\text{hi)}]

<u>Sample</u> values are calculated by the following equation:

(Reaction Rate * Cal Factor) + offset = sample value

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4.8.3 Multipoint Chemistries

Chemistries that fall into this category include drugs (such as theophylline, phenytoin, and tobramycin) and specific protein assays (such as IgG, IgM and IgA). Typically, the calibration process for these chemistries consists of five or six different levels of calibrators.

Unlike the first-order rate and endpoint chemistries, which exhibit a linear response to increasing concentration, the calibration curves for these chemistries exhibit a logistic (S-shaped) or other nonlinear relationship. For this reason, curve fitting interpolation techniques are employed to construct the calibration curve.

4.8.3.1 Calibration Formulas

The multi-point chemistries set calibration based on single replicates of each calibrator level (five or six levels). The standard curve is determined by use of one of several nonlinear math models. The CX4 program uses an iterative technique to calculate the curve parameters. A modified Newton iteration is used to choose values. The best-fitting calibration curve is determined by minimizing the sum of the squares of the difference between the observed response and the calculated response of each standard.

The following symbols are used in the math models presented below:

 $x \wedge y = x$ raised to the y power

 e^{-} = e raised to the power

R = sample response

Conc = standard or sample

concentration

 R_{\odot} = calculated response for a

zero sample

K_C = scale parameter

a, b, c = parameters which define the

nonlinear elements of the math model ("c" is not used

with model #1).

1. Model #1

Math model #1 is the four-parameter log-logit function most commonly used with reagents that use antibodies.

$$R = R_O + K_C * \left[\frac{1}{1 + e^{\frac{a}{2} - b} * In(Conc)} \right]$$

<u>Sample</u> values are determined using the calculated curve parameters and the math model. Values may be calculated directly as this model can be solved for concentration

$$\frac{1}{b} * \left[ln \left(\frac{R - R_{O}}{K_{C} - (R - R_{O})} \right) - a \right]$$

2. Model #2

Math model #2 is a five-parameter logit function.

$$R = R_O + K_C * \left[\frac{1}{1 + e^{-e - b} + \ln(Conc) - e + (Conc)} \right]$$

This function cannot be solved directly for concentration. The instrument uses an iterative method to determine the sample value.

3. Model #3

Math model #3 is a five-parameter exponential function.

$$R = R_O + K_C * \left[e^{a * ln(Conc) + b * ln(Conc)^2 + c * ln(Conc)^3} \right]$$

This function cannot be solved directly for concentration. The instrument uses an iterative method to determine the sample value.

4. Models #4 through #7

These models are reserved for future development.

5. Model #8

Math model #8 is an alternative to model #2, the five-parameter logit function.

$$R = R_O + K_C * \left[\frac{1}{1 + e^{-a - b} * In(Conc)} \right]^C$$

Note that c must be greater than zero.

6. Model #9

Math model #9 is an extension to model #1, the four-parameter log-logit function.

$$R = R_{O} + K_{C} * \left[\frac{1}{1 + c * e^{-a - b} * ln(Conc)} \right]$$

The "c" parameter is allowed to be either +1 or -1.

If c = +1, this is equivalent to model #1.

If c = -1, an alternative function is being used.

4.8.4 Drugs of Abuse (DAT) Chemistries

The Drugs of Abuse assays require three levels of calibrators. The calibration measures the separation between calibrators to ensure reagent integrity. The calibration factor generated is non-functional for sample result calculation.

The cutoff value for each DAT chemistry represents the mean reaction rate of the Low calibrator, and is reported in mA/min units on patient and control reports. The reaction rate of the samples is compared to the reaction rate of the Low(Cutoff) calibrator and reported out as POSITIVE or NEGATIVE. Cutoff values are stored in memory until the next successful calibration

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Section 5 PREPARING FOR OPERATION

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5.1 START-UP PROCEDURES

5.1.1 Boot/Power-up/Reset

The first software routine executed from a power-up or reset condition is the BOOT-up. BOOT software puts the instrument into a functional state by performing the system initialization, running initial in-line diagnostics, and loading the Operating System off the hard disk into RAM.

The initial BOOT-up will be performed by a Beckman Service Representative upon installation of the system (Paragraph 2.1). However, in the event of a reset or power failure, the system will require a subsequent BOOT-up. When the reset button located on the power LED display panel (Figure 5-1) is pressed or when power to the system has been restored, the BOOT-up routine will begin automatically. BOOT messages as well as the results of the in-line diagnostic tests will be printed (Figure 5-2). The monitor will display a copyright message. This is referred to as a full or hard reboot. A similar boot sequence occurs if the system is returned to operation by exiting the SYSTEM IDLE screen. However, the RAM checks and other in-line diagnostics are not initiated. This is referred to as a soft reboot. This process will only provide the display on the monitor.

Following a successful BOOT-up, the MASTER Screen is displayed and the system is ready for operation. Immediately following system boot-up, if a Temperature Control Error occurs, no action is required since the system temperature has not yet equilibrated. During temperature equilibration, which takes approximately five minutes, the message is invalid.

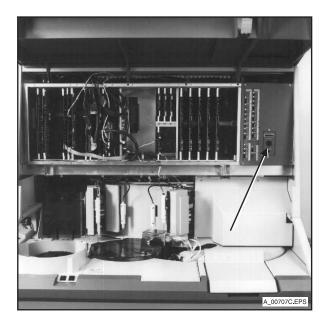


Figure 5-1. Reset Button

```
--- S Y N C H R O N
                      C X 4 B O O T - Version @1.00.15
    Configuration:
        Power Frequency: 60 Hertz
        CO2 Mode
                      : CO2 NOT in System
        Ram Size
                      : Four Megabytes
    -- CPU BOARD TEST
        - Test ROM
        - Test U46 PIC
        - Test U45 PIC
        - Test U21 PIT
        - Test U20 USART
        - Test Fail-Safe Ack circuit. (The system will not
          respond in case of the test failure. The CPU board
          will have to be replaced.)
        - Test WATCH DOG timer circuit
    -- RAM TEST
        - Test segment 03
        - Test segment 04
        - Test segment 05
        - Test segment 06
        - Test segment Ø7
        - Test segment Ø8
        - Test segment 09
        - Test segment ØA
        - Test segment ØB
        - Test segment ØC
        - Test segment ØD
        - Test segment ØE
        - Test sermont of
        rest segment 34
        - Test segment 35
        - Test segment 36
        - Test segment 37
        - Test segment 38
       - Test segment 39
       - Test segment 3A
       - Test segment 3B
       - Test segment 30
       - Test segment 3D
       - Test segment 3E
--- LOADING OPERATING SYSTEM...
```

Figure 5-2. Boot-up Displays

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A 01313C EPS

NOTE

The system supports the Okidata Microline 320 printer. For more specific information, refer to the printer manual that came with your system.

5.1.2.1 Setting Emulation Mode and Character Set (Mandatory)

The printer must be set to Epson FXe Emulation Mode and Character Set II to support print commands from the SYNCHRON CX DELTA Systems. The printer setup will be done at the initial installation of the Software Update for the SYNCHRON CX DELTA. The settings will remain intact through power outages and reboots. Should the settings be inadvertently changed, the following procedure can be followed to reset the Emulation Mode and Character Set:

- Press the MODE button on the printer control panel. This will take the printer off-line (the SEL light should go off and the MENU light should go on) and activate the commands located below the buttons (GROUP, ITEM, SET and PRINT). When these commands are utilized, the printer will print a line of information for that command. Refer to this printout as you follow the instructions.
- Press GROUP twice, or until the printed line reads:

General Control Emulation Mode IBM PPR

- Press SET once, or until the printed line reads:General Control Emulation Mode Epson FXe
- 4. Press GROUP twice again, or until the printed line reads:

Symbol Sets Character Set Set I

5. Press **SET** once, or until the printed line reads:

Symbol Sets Character Set Set II

- 6. Press PRINT if you want a printout of the internal printer programming. Refer to Figure 5-3 for baseline settings, keeping in mind that some operators have customized their printer and have different settings. In addition, some printer models may have different selection options. The PRINT function can be accessed anytime after pressing MODE, as in step 1.
- Press MODE to return the printer on-line and reactivate the commands located above the printer control panel buttons.

NOTE

Character Pitch is controlled by the SYNCHRON CX DELTA System. Refer to Report Setup in Section 6 of the Operating Instructions

5.1.2.2 Setting Page Length

The printer may be set to accommodate different paper (or page) lengths, for example A4 paper. The default setting on the printer is 11". The standard setting for A4 paper length is 11 2/3", but some manufacturers produce 12" lengths. To change the page length follow the instructions:

- Press the MODE button on the printer control panel. This will take the printer off-line (the SEL light should go off and the MENU light should go on) and activate the commands located below the buttons (GROUP, ITEM, SET and PRINT). When these commands are utilized, the printer will print a line of information for that command. Refer to this printout as you follow the instructions.
- Press GROUP three times, or until the printed line reads:

Vertical Control Line Spacing 6 LPI

Press ITEM six times, or until the printed line reads:

Vertical Control Page Length 11"

4. Press **SET** once (or twice), or until the printed line reads:

Vertical Control Page Length 11 2/3" (or 12")

- Press MODE to return the printer on-line and reactivate the commands located above the printer control panel buttons.
- To reset the page length to 11", follow step 1 through 3 and then press SET until 11" prints in the far right column. Complete the process with step 5.

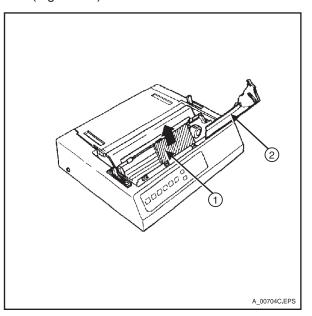
Font	Print Mode	Utility
Font	Pitch	10 CPI
Font	Style	Normal
Font	Sîze	Single
General Control	Emulation Mode	EPSON FXe
General Control	Graphics	Bi-directional
General Control	Max Receive Buffer	Full
General Control	Paper Out Override	No
General Control	Print Registration	O
General Control	Operator Panel Functions	Full Operation
General Control	Reset Inhibit	No
General Control	Print Suppress Effective	Yes
General Control	CPU Compensation	Standard
Vertical Control	Line Spacing	6 LPI
Vertical Control	Form Tear-Off	Off
Vertical Control		No
Vertical Control		No
Vertical Control	Auto CR	No
Vertical Control	Auto Feed XT	Invalid
Vertical Control	Page Length	11"
Vertical Control	Cut Sheet Page Length	11"
Symbol Sets	Character Set	Set II
Symbol Sets	Language Set	American
Symbol Sets	Zero Character	Slashed
Serial I/F Option	Parity	None
Serial I/F Option	Serial Data 7 or 8 Bits	8
Serial I/F Option		Ready/Busy
Serial I/F Option	Diagnostic Test	No
Serial I/F Option	Busy Line	SSD-
Serial I/F Option	Baud Rate	9600 BPS
Serial I/F Option	DSR Signal	Valid
Serial I/F Option	DTR Signal	Ready on Power Up
Serial I/F Option	Busy Time	200 ms
Font	Print Mode	Utility

Figure 5-3. Printer Control Panel Settings

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5.1.2.3 Installing the Ribbon Cartridge

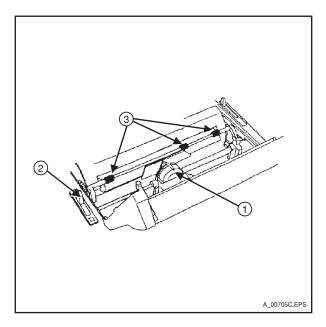
1. Remove the cover from the top of the printer (Figure 5-4).



- 1 Shipping Container
- 2 Access Cover

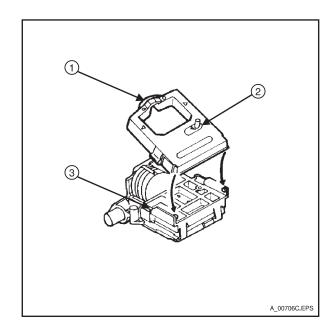
Figure 5-4. Removing the Cover

- 2. Position the printhead between the bail rollers. Make sure the bail is closed (bail lever toward back of printer). Refer to Figure 5-5.
- 3. Hold the ribbon cartridge with the knob facing up and the flat end toward the front of the printer (Figure 5-6).
- 4. Place the flat end into the ribbon plate, then lower the front of the cartridge over the printhead until it snaps into place (Figure 5-7).
- Remove any slack in the ribbon by turning the knob on the ribbon cartridge in the direction of the arrow.



- 1 Position of Printhead
- 2 Bail Lever
- 3 Bail Rollers

Figure 5-5. Printer Components



- 1 Ribbon Shield
- 2 Take-up Knob
- 3 Ribbon Plate

Figure 5-6. Placement of Ribbon Cartridge

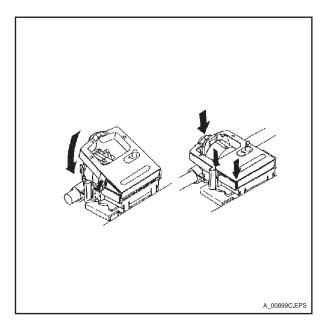
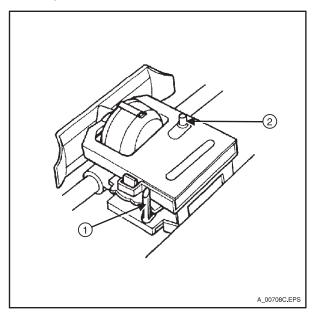


Figure 5-7. Loading the Ribbon Cartridge

- 6. Located on the left side of the ribbon cartridge holder is a head-gap adjustment lever (Figure 5-8). The position of this lever sets the printhead gap which varies according to the type of paper and number of copies printed. Set the lever to "1" for one or two part forms, "2" for three or four part forms, or "3" for envelopes or extra thick paper.
- 7. Replace the cover.



- 1 Headgap Lever
- 2 Take-up Knob

Figure 5-8. Head-Gap Adjustment Lever

5.1.2.4 Removing the Ribbon Cartridge

- 1. Remove the cover from the printer (Figure 5-4).
- 2. Place the column indicator against the platen (roller). Slide the printhead to the center of the printer (Figure 5-5).
- 3. Grasp both sides of the ribbon cartridge over the printhead (Figure 5-9). Without bending the ribbon shield, first pull the cartridge up from the printhead and then pull it up and out.

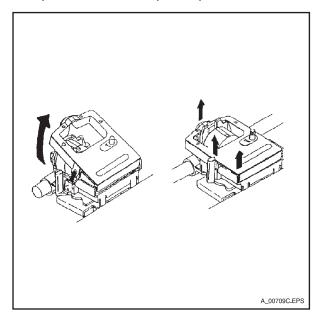


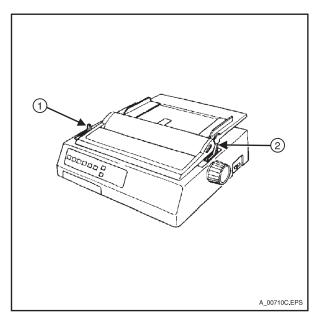
Figure 5-9. Removing the Ribbon Cartridge

4. Refer to Paragraph 5.1.2.3 for instructions on installing a ribbon cartridge.

5.1.2.5 Loading Fan-fold Paper

- 1. Open the access cover and rear cover from the printer (Figure 5-4).
- 2. Make sure the paper lever is in the forward position (Figure 5-10).
- 3. Open the bail (bail lever forward) (Figure 5-10).

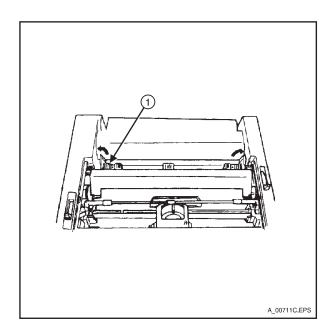
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- 1 Bail Lever Forward
- 2 Paper Lever Forward

Figure 5-10. Loading Paper

 Open the tractor covers (Figure 5-11). To make inserting the paper easier, center the printhead and pull the column indicator away from the platen.



1 - Tractor Cover

Figure 5-11. Tractor Covers

- 5. Pull the paper through the opening between the printer and the rear cover.
- There are reference marks on the printer to show the recommended left edge position for the two most common paper sizes. Place the first two sprocket holes on each side of the page over the pins.

To adjust the tractors for the width of the paper, pull the lock levers forward, slide the tractors into position, then push the levers back to lock.

NOTE

Do not position the left edge of the paper more than 1/2 inch from the end of the platen. The paper must cover the groove in the left side of the platen; if it doesn't, the printer will signal the "paper out" alarm.

- Replace the rear cover on the printer. Make sure the paper separator is flat on the printer.
 Open the guide wire, then close the access cover.
- 8. Turn the printer ON. Pull the bail lever forward. The paper will automatically feed into the printer. (Refer to Paragraph 5.1.2.6 for instructions on how to use the control buttons located on the front of the printer). Push the bail lever back close to the bail.
- 9. If the top-of-form is properly set, place the printer off-line by pushing SELECT on the front control panel (the SELECT light will go out). Press TOP OF FORM. If the top-of-form is not properly set, refer to 5.1.2.6, step 1.
- 10. Press the FORM FEED button. The printer will feed the paper to the next top-of-form. If the top-of-form stops at the paper perforation, the printer is set properly.
- 11. Place the printer back on line by pressing **SELECT**. The printer is now ready for use.

5.1.2.6 Printer Control Buttons

Refer to Paragraph 3.2.5 for a functional definition of the lights and buttons located on the front panel of the printer (Table 3-1). To set the TOP OF FORM, the printer must be off-line (the SELECT light is out).

1. Top of Form

- (a) Press the **SELECT** button to place the printer off-line (SELECT light OFF).
- (b) For proper placement, line up the perforation between the sheets of fan-fold paper with the upper red line on the paper shield.
- (c) Press the TOP OF FORM button. Press the SELECT button to place the printer to ready (SELECT light ON). If the printer is off, the top of form is automatically set when the printer is turned on. The top of form is now set.

2. Form Feed

- (a) Press **SELECT** to place the printer off line (SELECT light off).
- (b) Press the FORM FEED button. The printer will feed the paper to the next topof-form.
- (c) Press **SELECT** to place the printer back on line (SELECT light on).

3. Line Feed

- (a) Press **SELECT** to place the printer off line (SELECT light off).
- (b) Press the **LINE FEED** button to advance the paper one line. Repeat for each line.
- (c) Press **SELEC**T to place the printer back on line (SELECT light on).

5.1.3 Diskette Handling

The 3.5-inch (8.9 cm) diskette is designed for use in the micro-floppy disk drive to transfer supplemental information which is not stored on the hard disk to and from the instrument, or to perform an archive function for Quality Control data. The following paragraphs are a guide for the handling procedures on the diskette and disk-drive unit.

5.1.3.1 Proper Care of Diskettes

Each diskette is permanently sealed in a plastic cartridge. Protect each diskette by taking the following precautions:

- 1. Diskettes not intended for immediate use should be placed in a storage compartment.
- 2. Do not attempt to touch or clean the diskette surface. Abrasion may cause loss of data.
- Do not expose the diskette to extreme heat or direct sunlight. Exposure to temperatures in excess of +51.6℃ (125°F) may cause irreversible damage.
- Never place the diskettes near a magnetic field.
 This will result in permanent damage. A common source of a magnetic field is electrical equipment.
- 5. Never remove a diskette from the drive when the yellow or "DRIVE LED" lamp is ON.
- Press the disk-drive eject button BEFORE turning system power on or off or during a power outage (the disk-drive head may damage a diskette when power is restored).

5.1.3.2 Loading Diskettes

Although the main operating program, patient data, control data, and diagnostics reside on the hard disk, there may be a need to access the micro floppy disk drive (e.g., updates to the software, loading calibrator diskettes, or archiving Quality Control data). Use the following procedure to load a diskette into the disk drive:

- 1. Ensure that the write-protect tab is closed (Figure 5-12).
- 2. Insert the diskette with the label on the top side into the drive opening (Figure 5-13).
- 3. Push in the diskette until the latching mechanism is actuated.
- 4. To remove a diskette push the eject button. The diskette will automatically eject.

5.1.4 Backup Diskette

The system backup procedure is intended to provide a method of backing up and restoring certain setup and data files.

The Backup Diskette Set consists of four (4) 3.5-inch floppy diskettes. Each diskette is a double sided, high density, blank, unformatted disk.

The formatting process is included in the Backup Procedure.

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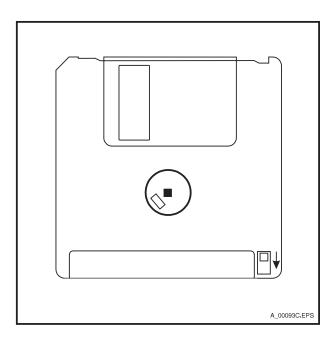


Figure 5-12. Write-Protect Operation



Figure 5-13. Inserting a Micro-Floppy Diskette

CAUTION

If a diskette appears damaged, do not insert it into the disk drive. A scored diskette may damage a disk drive and subsequently all other diskettes placed into that drive. A scored diskette may also indicate a dirty or damaged disk drive. Call the Beckman Clinical Support Center for assistance 1-800-854-3633. International customers should contact their local Beckman office (Appendix A).

5.1.4.1 Backup Procedure

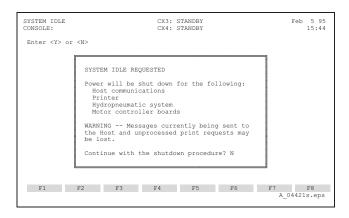
The backup procedure should be performed following 1) a change in alignments, and/or 2) a parameter setup file change. The operator can select a full backup (includes setup files and alignment data), or backup of alignment data only. A change to alignment should be followed by backup of at least alignment data. Changes to setup parameters should be followed by the full backup.

Procedure	Setup File
System Setup Procedures	System Setup Files
Setpoint Modification and	Calibration Bar Code Files
Slope/Offset Adjustment	Calibration Data Base File
	Chemistry Data Base File
Flash Delay Procedures	Flash Delay
Flash Power Procedures	Flash Power
Lamp Alignment Procedures	
Lamp Calibration Procedures	Lamp Cal/Lamp Stat
Temperature Diagnostics	EEprom
Probe/Mixer Rotary and	Phase
Vertical Alignment Procedures for Sample and Reagent Systems	ISE Probe Height
Probe and Mixer Height	
Adjustment of Both Sample and Reagent Systems	
Probe Alignment Procedure in ISE Motion System	CX3 Height
	F Matrix Quality Control Data Base File Reference Ranges Data Base File
	rioloronoo riangoo bata base riic

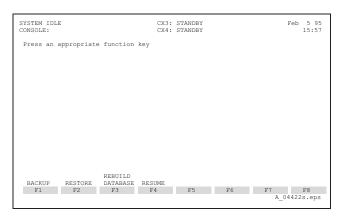
Perform the following procedure to back up setup parameters and/or alignment data:

 Verify that the system is in STANDBY and displaying the MASTER Screen. Press the SYS-TEM IDLE key.

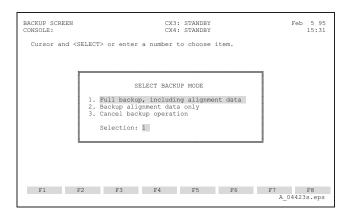
System power for the printer, host communications, hydropneumatics and motor controller boards will be shut down. Type Y to continue; N to exit.



3. Press F1 BACKUP.



The backup options are displayed.



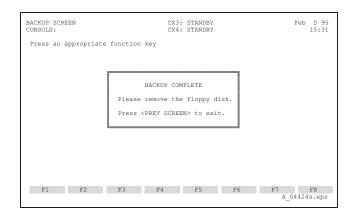
Choose to backup all data (selection 1), or only alignment data (selection 2). Choosing selection 3 cancels backup and returns the operator to the IDLE Screen.

Insert the diskette that will be used to back up files.

WARNING

Inserting the diskette will prepare the floppy disk by ERASING it before copying data.

- 5. Press **ENTER** to initiate the backup procedure.
- The diskette is formatted, initialized, verified and prepared (directories are being created).
 When the diskette is ready, the console hard disk begins to load backup and version number files
- 7. When backup is complete, the operator is notified on the screen.



- 8. Remove floppy disk.
- Press PREV SCREEN to return to the SYSTEM IDLE Screen.
- Follow instructions in 5.1.4.3 Resuming Operation.

5.1.4.2 Restore Procedure

WARNING

Performing the restore function deletes some or all of the following files (depending on the areas restored) from the hard disk (when restore is complete):

Alignment Files
Reagent records
Instrument result records
Patient sample records
Sector data base
Calibration requests
Special calculations

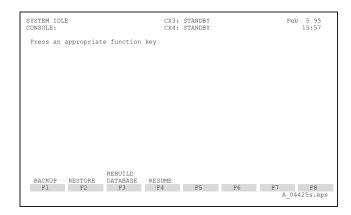
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NOTE

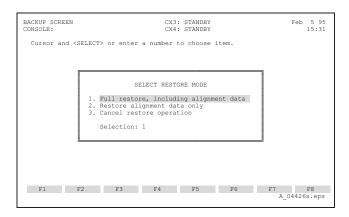
If the software version on the backup diskette is different from the system software version, the RESTORE function cannot be performed.

Perform the following procedure to restore backed-up setup parameters and data files.

 While in STANDBY and displaying the MAS-TER Screen, press the SYSTEM IDLE key. A confirmation window will display. Type Y and press ENTER to continue.

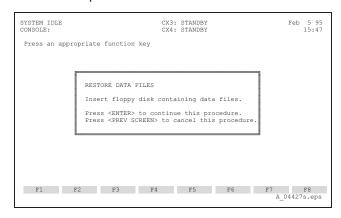


2. From SYSTEM IDLE Screen, press **F2 RESTORE**. The Restore options are displayed.

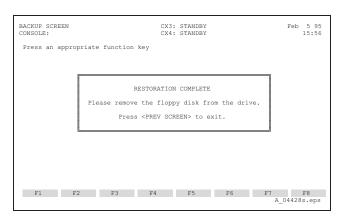


To restore alignment and setup data, choose selection 1. To restore alignment data only, choose selection 2. To cancel the Restore function, choose selection 3. Restore takes approximately 5 minutes.

3. The following message is displayed. Insert the backup diskette into the disk drive.



- 4. Press ENTER. The Restore function checks the version file number for a version number on the floppy diskette and the console hard disk. If the version numbers match, the message area on the screen displays "Copying Data Files from the Floppy Disk - Please Wait".
- When complete, the message "Restoration Complete" is displayed. Remove the backup diskette from the drive.

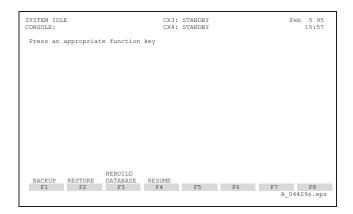


- Press PREV SCREEN to return to the SYSTEM IDLE Screen.
- Follow instructions in 5.1.4.3 Resuming Operation. When system is operational, remember to toggle Host Communications ON.

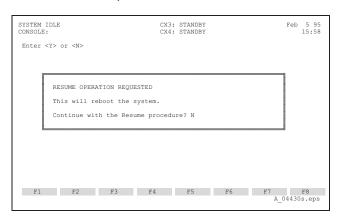
5.1.4.3 Resuming Operation

The RESUME function reboots the system and returns it to normal operation.

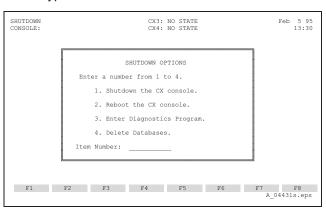
 From the SYSTEM IDLE Screen, press F4 RESUME.



2. Press Y to proceed with the RESUME function.



- 3. Press PREV SCREEN when prompted.
- Cursor and select 2. Reboot the CX console, or type 2 ENTER.



The system will reboot and eventually display the MASTER Screen. Host Communications should be toggled ON following RESTORE.

5.1.5 Database Recovery

In the event of a fatal crash or power outage, the system will attempt to recover files and databases which may have been impacted. Consistency between Calibration, Reagent, Quality Control and Sector information will be ensured through a database recovery program which resides in the software (Figure 5-14). If corrupt setup files and/or databases are found, the operator will be notified via the IDLE Screen; the display will identify the areas where data may have been lost. The areas which may be affected/displayed are listed below. Press **PRINT SCREEN** to obtain a list of the areas displayed on the screen before proceeding.

Calibrator setpoints/limits Reagent Status

Calibrator barcode assignments Within Lot Status

Calibration results Reference Ranges

Calibrator cup assignments Results

Chemistry definitions Sample programming

QC definitions/cumulatives Manual cup assignments

QC results

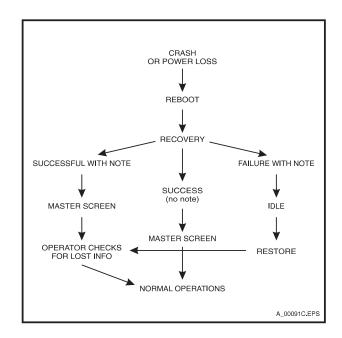


Figure 5-14. Flow Diagram of Recovery Task for Software

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Review the appropriate areas as follows:

<u>Calibration</u> (results, setpoints, acceptance limits, barcode assignments, cup assignments, slope/offset).

Check all setpoints and acceptance limits; if any are missing or incorrect, make adjustments to appropriate chemistries or reload the appropriate calibrator diskette. Check to see if any previously calibrated chemistries have a status of Calibration Required. Also, chemistries which may have had a status of Requested and Programmed may have returned to their previous status. Check Cal Cup Assignments in Sector mode, or barcode assignments if running in Barcode mode. If calibrator barcodes are missing, check to make sure all reagents are loaded and/or reload calibrator diskettes.

Chemistry Definitions

Check the Chemistry Configuration screen for missing chemistries. Configurable chemistries can be listed using the print option. Beckman chemistries can be recovered by loading the last diskette in the software installation diskette set using the Chem Update function (Special Functions). Contact the Beckman Clinical Support Center or your local service representative for more complete instructions. If a User Defined chemistry is missing, it will need to be redefined from the User Defined screen.

In either case (Beckman or UDR chemistries), the missing chemistry will have been removed from all related sample and result records.

Check the Reportable Range function and print out the listing to verify that the defined ranges are not lost. Reenter any ranges that are no longer available.

Quality Control

If QC files are corrupted, the QC cumulative statistics may not have been updated. This may also occur if the operator was deleting a point in the QC Log at the time of the power failure/crash. Check the Event Log for a list of any QC file numbers for which cumulative statistics may have been recalculated, or for any QC results which may have been deleted due to the loss of a control record.

Reagent Status

Check status of all reagents. If any previously loaded reagents do not appear in the status display, check chemistry configuration to make sure that the chemistry was not deleted. If the chemistry has been deleted, follow the instructions above for "Chemistry Definition."

Within Lot Status

Check status of all within-lot chemistry reagents. If any previously loaded reagents do not appear in the status display, check chemistry configuration to make sure that the chemistry was not deleted. If the chemistry has been deleted, follow the instructions above for "Chemistry Definition."

Reference Ranges

No specific action should be taken if Reference Ranges are lost. The operator should view the Reference Ranges and reenter any ranges that are no longer available.

Results

This indicates that one or more result records was deleted. Operators will need to rerun the sample.

Sample Programming

If the sample database was affected, either a chemistry has been deleted from a sample program, or a result record is missing. Check sample programs which have not been run and/or recalled results for completed chemistries. Make sure that the missing chemistry is still configured; if it is not, follow the instructions outlined above under "Chemistry Definition" and either add the restored chemistry back into the affected sample programs or rerun the sample for the chemistry.

Manual Cup Assignments

Check all manual cup assignments for samples not yet run. If any previous assignments are missing, make the assignment again.

If any discrepancies are found, the RESTORE function should be performed using the Backup diskette (refer to Section 5.1.4.2 for detailed instructions). In the event that RESTORE is unsuccessful, a message will be displayed informing the operator with the recommendation that a reload of software may be indicated. Customers should contact their local Beckman representative or the Beckman Clinical Support Center for assistance.

If the RESTORE is successful, operators should check the previous list of items, depending on the areas which were affected.

5.1.6 Version Upgrade Compatibility

Users of CX4CE/CX7 and CX4/CX7 DELTA instruments generate a large amount of data and input a significant amount of user-specific information.

When upgrading software versions, the system will convert and transfer all databases, alignment files, and setup information into the new operating software version. This feature eliminates the need for operators to reenter setup and alignment information, and also prevents the loss of important data. The data conversions will take place for:

CX Alignment Data Sample Programming and Results Chemistry Database Sector Programming Calibrator Database Special Calculations Reagent Database System Setup Database Reagent Lot Database Report Setup Database Calibrator Barcode IDs Host Setup Database Control Ranges and Results Sample Programming Setup Calibrator Sample Programs Reportable Ranges Calibration Results

These records are copied and saved on a separate part of the hard drive, then merged into the new software version as soon as loading is complete.

5.2 PROGRAM STRUCTURE

Reference Ranges

As the operator, it is important to understand the interface philosophy before you can comfortably interact with the instrument. The interface between operator and instrument is based on a tree structure which branches out from the most frequently used operations down to the least accessed functions. This hierarchy is illustrated in Section Six, Operating Procedures.

Note that there are only three major levels and that these, which represent all of the functions available to you, can be accessed from the MASTER Screen using a minimum of time and keystrokes. The system is designed so that the highest percentage of time you spend interacting with the computer is at the first level.

Details of each function are described in Section Six.

5.3 SCREEN FORMAT

The SYNCHRON CX System functions interactively by means of prompts. The operator communicates with the system by responding to these prompts as they appear on the screen. Familiarization with the screen format and keyboard layout will help the operator understand how this communication takes place.

A screen is divided into several distinct areas, each with a specific purpose. For easy reference, these areas are the same on every screen of the interface. Figure 5-15 illustrates these features:

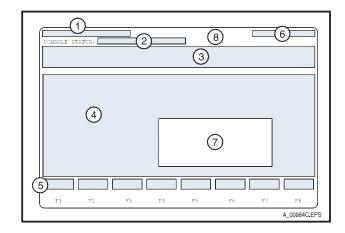


Figure 5-15. Screen Format

- SCREEN TITLE The title of the screen the operator is currently accessing is always displayed in this area for easy reference.
- CONSOLE STATUS This area indicates tasks currently taking place which directly involve the console. Examples of console status include: Sending to Host, Receiving from Host.
- MESSAGE DISPLAY This two-line boxed area is reserved for operator instructions and operator errors.
- MAIN DISPLAY Displays the specific screen information and is reserved for operator interaction.
- FUNCTION KEYS Consists of eight (F1 -F8) multi-function key labels accessible through the corresponding hard keys (F1 - F8) on the keyboard. Any key label displayed is functional only for the current screen.
- DATE/TIME A real-time clock is displayed in this area to indicate the current date and time. The format is Month/Day/Year and Hours:Minutes (military designation).
- WINDOWS Windows serve as a bridge between two related screens or give the operator access to additional information related to a screen.
- 8. CX3 and CX4 STATUS This area indicates the current operating state of the instrument whether in standby or operation. Status

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updates with every change. Examples of operating states include: Running, Priming, or Homing.

5.4 MASTER SCREEN

The MASTER Screen is the trunk of the operatorinterface screen tree. It provides access to the most frequently used screens of the operator interface: Sample Programming, Reagent Load, Calibration, Special Functions, Quality Control, Sample Carousel Status and System Parameters (Figure 5-16). In addition, the MASTER Screen displays sample programming and chemistry processing information:

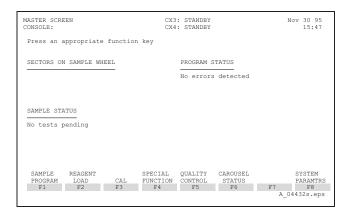


Figure 5-16. Master Screen

CX3 reagent volume low

The area labeled SECTORS ON SAMPLE WHEEL displays the sectors currently being processed.

PROGRAM STATUS is a summation of any status messages which may exist given the current programmed information. The status messages indicate that a requested chemistry may not be run due to a current status of the reagent involved.

NOTE

These status messages appear on the MASTER Screen only if they correspond to a chemistry that is currently programmed. (For a comprehensive status matrix, refer to the Appendix.)

The following errors/status messages are identified in this area:

Calibration overridden
Cal time extended
Failed calibration
Calibration timed out
Reagent not on board
Calibration required
Cal requested - cups not assigned
Chemistry bypassed
Failed calibration
Level sense error
Zero tests available
Reagent date expired
Reagent exceeds days usable

These messages pertain to those conditions which, if not corrected, will prevent a chemistry from being processed or will flag the result in the Instrument Code section of the report.

If any of the above messages appear in the PROGRAM STATUS field, refer to the appropriate status screens to determine the specific chemistry in error: Sector Status (Paragraph 6.4.1), Reagent Status (Paragraph 6.2.4), Calibration Status (Paragraph 6.3.1), or the Pre-Run Summary Report (Paragraph 6.4.6).

SAMPLE STATUS messages indicate that a sample has been processed in which a programmed test could not be completed given the current operational state of the system. To identify the specific sector/cup position containing the pending test, refer to the Post Run Summary Report (paragraph 6.4.7). Manual cup assignments are also noted in this area with a lower case "m" following the sector number.

5.5 AUTOLOADER OPERATION

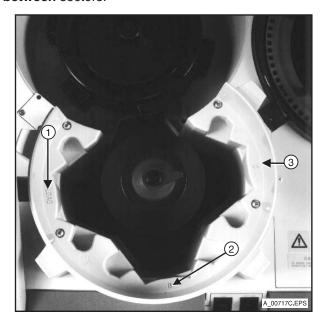
The autoloader is designed to allow for the automatic, continuous loading of sectors on to the sample carousel, and for the unloading of sectors from the sample carousel (sectors are unloaded if all samples on the sector are in progress and if no ORDAC flags are set). Additionally, it provides a mechanism for placing STAT samples on the system without interrupting ongoing sample processing and analysis.

NOTE

If the system is in STANDBY, sectors can be loaded directly onto the sample carousel before pressing **START** to begin the run.

5.5.1 Starting and Stopping the Autoloader

Place up to three sectors on the autoloader starting from the LOAD position, followed by positions B and C (Figure 5-17). Do not leave empty autoloader positions **between** sectors.



- 1 LOAD Position
- 2 Position B
- 3 Position C

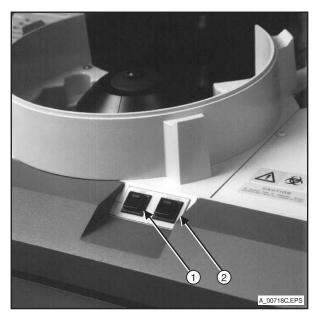
Figure 5-17. Autoloader

NOTE

When the system is in STANDBY, sectors may be manually placed on the sample wheel in addition to the autoloader (for a total of 8 routine sectors).

Sectors may be placed in any order; they do not have to be loaded in the order programmed. The sectors are routinely processed on a first on/first sampled basis unless it is a sector reserved for calibration, or one containing a STAT sample. Once the sectors have been loaded, there are two ways to initiate the autoloader cycle:

- 1. When the system is in STANDBY, pressing START will cause the autoloader to cycle.
- When the system is running, the operator can initiate an autoload cycle by pressing one of two illuminating pushbuttons labeled LOAD and STAT LOAD, located on the front of the autoloader assembly (Figure 5-18).



- 1 LOAD Button
- 2 STAT LOAD Button

Figure 5-18. Autoloader Pushbuttons

The light associated with either button may indicate the following:

OFF Under normal circumstances, the lights will always be OFF. This indicates that the autoloader is not scheduled to cycle. Operator can load or unload sectors at this time. When the system is running, one of the autoload buttons must be pressed to activate a cycle if additional sectors are to be loaded onto the sample wheel.

ON Feedback in response to pushing the LOAD, STAT LOAD, or START button. The light will remain ON until the autoloader cycle begins (see FLASHING) or until one of the conditions for stopping the autoloading is encountered (see below). The operator can load or unload sectors at this time, however, the autoloader is already scheduled to cycle; the buttons do not need to be pressed.

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NOTE

Pressing **START** will light the LOAD button.

FLASHING

Indicates that the autoloader is about to begin or is in an operating cycle. The flash will begin approximately 5 seconds prior to the actual cycle and end when the assembly is in its "home" position. It is not recommended that the operator load or unload a sector while the light is flashing.

The autoloader will be activated automatically when all samples on the sector are in progress, and if all conditions for ORDAC have been met. The sector will be unloaded even if there are no other sectors to be loaded. The autoloader will stop cycling automatically under three conditions:

- 1. When the first empty autoload position is encountered.
- When a sector that has been unloaded after all possible tests have been run is reloaded. This indicates that the autoloader has cycled all three positions without encountering a sector that had not been previously loaded.
- 3. All positions are filled on the sample carousel.

5.5.2 LOAD Button

The LOAD button is used to process sectors with routine samples. Of the six sector positions on the sample wheel, five are available for sectors which contain routine samples. Pressing the LOAD button signals the microprocessor that the sector(s) placed on the autoloader will be loaded into one of the five routine positions on the sample wheel WHEN A POSITION BECOMES AVAILABLE.

- 1. If there is an existing empty routine position on the sample wheel, the sector will be loaded within the next load cycle (3 to 4 spin cycles).
- 2. If all five routine positions are occupied, the new sector will be loaded when a sector is unloaded (all possible tests scheduled are running and/or all ORDAC conditions have been met) by the autoloader. In this case, the time it takes to load the new sector will depend on how long it takes to aspirate sample and dispense reagent for all programmed tests on the sector, and to process samples meeting ORDAC conditions.

3. If the LOAD button is pressed instead of the STAT LOAD button for a sector containing STAT samples, the sector will be placed into a routine sample wheel position and is subject to a possible delay in being loaded if no routine positions are available. However, once loaded, the STAT sample will be scheduled to be processed as first priority.

5.5.3 STAT LOAD Button

The STAT LOAD button is used to process sectors with STAT samples. Of the six sector positions on the sample wheel, one is available for sectors which contain samples that have been programmed as STAT. Pressing the STAT LOAD button signals the microprocessor that the next sector to be loaded will be placed into the available STAT position on the sample carousel within the next possible load cycle.

Once loaded, the tests programmed as STAT are scheduled as first priority and will be analyzed before all the routine samples currently scheduled on the sample carousel. If there are open routine positions on the sample carousel, then the STAT sector will be unloaded when all tests for that sector are running and/or all ORDAC conditions have been met.

In the event that all routine positions are full and a STAT sector has been loaded, the STAT sector will remain on the system. If the STAT sector needs to be unloaded prior to the end of the run, press the STAT LOAD button and leave the position marked "LOAD" on the autoloader empty in order to have a position available on the sample wheel for future STAT samples.

If STAT LOAD is pressed instead of LOAD for a sector containing routine samples, the sector will be placed into a STAT sample wheel position but the programmed tests will be scheduled as routine samples making this position unavailable for STAT sectors until completed.

If routine samples were programmed and intermixed with a STAT sample on the same sector, the STAT sample would be completed at first priority but the routine samples on the same sector would be scheduled behind all the other routine sectors currently residing on the sample wheel. If this sector is occupying a STAT position on the sample wheel, the position will not be available for loading of additional STAT sectors until all the routine tests have been sampled and are no longer needed for ORDAC testing.

5.6 SYSTEM SHUTDOWN

If the system is to remain in STANDBY for an extended period of time (e.g., overnight or over a weekend), it is recommended to place the CX4CE/CX4 DELTA or the CX7/CX7 DELTA in an idle condition. By placing the system in IDLE, the power to the following modules are turned off:

Hydropneumatic System Motor Controller Boards

It is also recommended that the system be placed in IDLE before resetting or turning the power off. Doing so results in a shorter boot-up time.

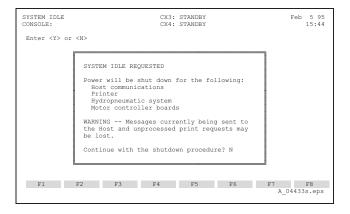
To initiate a system idle, perform the following sequence:

 Wait until the system status for CX3 and CX4 reads "STANDBY".

CAUTION

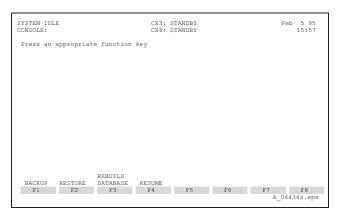
Ensure that the system is not transmitting data to a host. Data may be lost if system is placed in IDLE before transmission is completed.

- 2. Press SYS IDLE.
- 3. Press **Y** at the confirmatory prompt. The modules defined above will shut down and the monitor will display the IDLE Screen.

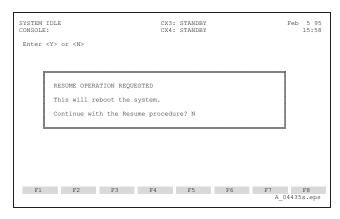


To resume system operation, perform the following steps:

1. Press F4 RESUME.

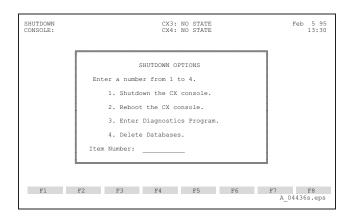


2. Press **Y** to the confirmatory prompt.



- Press PREV SCREEN when prompted.
- Cursor and SELECT 2. Reboot the CX console, or type 2 ENTER

The system will begin a boot sequence. When completed, the monitor will display the MASTER Screen.



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5.6.1 Extended Shutdown

If the system is to be moved or will not be operated for an extended period of time, (i.e., more than 1 week) the following procedure is recommended:

CX3

- Remove all reagents from reagent compartment. Wipe the exterior of the straws with lintless tissue. Empty Wash Concentrate bottle and rinse 3 times with DI water.
- Install a small empty waste bottle in the reagent tray and place the CO₂ Alkaline Buffer return line (line #82) into the waste container.
- Prime all CX3 reagents/modules five (5) times with air as follows:
 - (a) From the MASTER Screen, press **F4 SPECIAL FUNCTION**.
 - (b) Cursor and SELECT 1. Prime, or type 1 ENTER. Refer to Paragraph 6.5.2 Prime for detailed information on priming the system.
 - (c) Cursor and SELECT all CX3 reagents/ modules which are located on the right side of the Prime Screen, or press F3 PRIME ALL CX3.
 - (d) Press F1 START PRIME to initiate priming.
 - (e) Type **5 ENTER**.
- Prime all CX3 reagents/modules 30 times with DI water as follows:
 - (a) Place all reagent straws (except Alkaline Buffer drain line #82) in bottle of DI water. (the reagent straws will not all reach the same bottle of DI water, therefore it will be necessary to use more than one bottle.)
 - (b) Cursor and SELECT all CX3 reagents/ modules which are located on the right side of the Prime Screen, or press F3 PRIME ALL CX3.
 - (c) Press F1 START PRIME to initiate priming.
 - (d) Type 30 ENTER.
- 5. Upon completion of the DI water prime, remove all straws from the DI water wash bottle and prime all CX3 reagents/modules 30 times with air as follows:

- (a) Cursor and SELECT all CX3 reagents/ modules which are located on the right side of the Prime Screen, or press F3 PRIME ALL CX3.
- (b) Press F1 START PRIME to initiate priming.
- (c) Type 30 ENTER.
- Remove the waste container used in Step 2, and cap all reagents.
- Release one side of each peri-pump tubing. Tie
 a rubber band on the loose end of the peripump tubing and hook the rubber band to the
 peri-pump.
- Remove the NA MEASURE electrode and NA REFERENCE electrode from the flow cell. Ensure the reference electrode is labeled as such.
- 9. Dry the ports with lintless tissue. Reinstall both retainers into the flow cell. Cover openings with a strip of masking tape.
- 10. Prepare electrode soaking solution (refer to Section 4.26 in the Diagnostics and Troubleshooting Guide). Add soaking solution to the sponge in two electrode caps. Use these to cap both NA MEASURE and NA REFERENCE electrodes. Place quad-rings into a small plastic bag.
- Remove the CO₂ and CO₂ REF electrodes from the flow cell. (Ensure the reference electrode is labeled as such.) Remove and discard their membranes.
- 12. Place both membrane retainers into their own labeled plastic bags.
- Place a black plastic cap on both of the electrodes.
- 14. Remove the CHLORIDE, POTASSIUM, and CALCIUM electrodes from the flow cell and place their quad-rings into a plastic bag.
- 15. Place a WHITE plastic protective cap on the POTASSIUM and CALCIUM electrodes.
- Place a BLACK plastic protective cap on the CHLORIDE electrode.
- Place all of the ELECTROLYTE electrodes and the plastic bags (containing membrane retainers and quad-rings) in a box.
- Remove tubing from the CO₂ Alkaline Buffer (line #77), Flow Cell (line #72), and the EIC Drain (Line #74) solenoid valves.

- 19. Release the pressure bars on the pinch valve assembly. Place a strip of masking tape across each bar to retain them to the tub.
- 20. Clean the inside of the Electrolyte Injection Cup with a cotton-tipped applicator stick and DI water. Dry with a lintless tissue.
- 21. Remove the BUN and GLUCOSE electrodes and set them aside for cleaning. Clean the ports for these electrodes with a lintless tissue moistened with DI water.
- 22. Remove the stirrer bar from the BUN module. Clean with a lintless tissue moistened with DI water. Place stirrer bar into a labeled plastic bag.
- 23. Repeat this procedure for the GLUCOSE and TOTAL PROTEIN or CALCIUM stirrer bars, again placing them in properly labeled plastic bags.

NOTE

DO NOT INTERMIX STIRRER BARS

- 24. Remove the stirrer bar from the CREATININE module and clean with 1% HCL or diluted CO₂ Acid Reagent (1 part CO₂ Acid with 4 parts DI water). Rinse with DI water. Place stirrer bar into a labeled plastic bag.
- 25. Clean the inside of the CREATININE reaction cup with 1% HCL or diluted CO₂ Acid Reagent (1 part CO₂ Acid with 4 parts DI water). Rinse with DI water using a cotton tipped applicator. Dry with a lintless tissue.
- 26. Clean the inside of the BUN, GLUCOSE, and TOTAL PROTEIN or CALCUIM reaction cups with DI water using a cotton tipped applicator. Dry with another lintless tissue
- 27. Remove and discard the membrane from the GLUCOSE electrode.
- 28. Clean the body, sleeve and "O-ring" of the GLUCOSE electrode with DI water. Reinstall the electrode into the GLUCOSE module.
- 29. Clean the face of the BUN electrode using a lintless tissue moistened with 70% ISOPRO-PYL ALCOHOL. Clean its sleeve and quad-ring with DI water. DO NOT APPLY MOLYCOTE.
- 30. Re-install the electrode into the BUN module.
- 31. Clean the inside of the CX3 sample probe with the cleaning stylus. (Beckman P/N 439606). Clean the outside of the probe with 1% HCL or diluted CO₂ Acid Reagent (1 part CO₂ Acid with 4 parts DI water). Rinse with DI water.

CX4

- 1. Remove all reagent cartridges.
- Shut down the hydropneumatic system as follows:
 - (a) From the MASTER Screen, press F4 SPECIAL FUNCTION.
 - (b) Cursor and SELECT 6. Maintenance Procedures, or type 6 ENTER. (Refer to Section 9 for a complete description of maintenance procedures).
 - (c) Cursor and **SELECT** 4. Hydropneumatic Shutdown or type **4 ENTER**.
- 3. Remove both CX4 dilute wash bottles, CX4 wash concentrate bottle, and Probe Rinse Solution bottle. Empty contents.
- 4. Rinse the four bottles with DI water three (3) times. Fill each bottle with DI water.
- 5. Replace the bottles on the instrument.
- Press ENTER to exit Hydropneumatic Shutdown and turn the hydropneumatic module back on.
- 7. Press **F8 MAINT MENU** to return to the Maintenance Menu Screen.
- 8. Perform a cuvette wash as follows:
 - (a) Cursor and SELECT 2. Cuvette Wash, or type 2 ENTER.
 - (b) Repeat Step (a) two (2) more times.
- Prime Internal Probe Wash three (3) times as follows:
 - (a) Press MASTER SCREEN.
 - (b) Press F4 SPECIAL FUNCTIONS.
 - (c) Cursor and SELECT 1. Prime, or type 1 ENTER.
 - (d) Cursor and SELECT Internal Probe Wash.
 - (e) Press **F1 START PRIME**. Repeat this step for a total of three (3) primes.
- 10. Shut down the hydropneumatic system as follows:
 - (a) Press MASTER SCREEN.
 - (b) Press F4 SPECIAL FUNCTION.
 - (c) Cursor and SELECT 6. Maintenance Procedures, or type 6 ENTER.
 - (d) Cursor and **SELECT** 4. Hydropneumatic Shutdown, or type **4 ENTER**.

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- Remove the dilute wash bottles, wash concentrate bottle, and Probe Rinse Solution bottle.
 Empty the contents and replace on the instrument.
- Turn the external DI water valve leading to the instrument OFF.
- Turn the internal DI water valve in the hydropneumatic module OFF.
- Press the AUX circuit breaker to the OFF position. Press the MAIN circuit breaker to the OFF position.

Floppy Disk-Drive System

- 1. Press SYSTEM IDLE.
- 2. If the instrument is to be moved, insert the floppy-disk shipping guard supplied with the instrument for magnetic-head protection into the floppy drive. If this static guard is unavailable, insert any diskette (e.g., an outdated calibrator diskette) into the floppy drive.

To resume system operation from an extended shutdown, perform the following steps:

CX3

- Install a new membrane onto the CO₂ MEA-SURE electrode and return the electrode to the appropriate port of the flow cell (refer to Section 4 of the Diagnostics and Troubleshooting Guide for detailed procedure).
- Return the CO₂ REFERENCE electrode to the appropriate port of the flow cell.
- Return the NA MEASURE electrode to the appropriate port of the flow cell.
- 4. Clean the surface of the NA REFERENCE electrode with Electrolyte Reference reagent and set aside. Place one drop of 70% isopropanol on the reference electrode side (right side) of the carbon bridge and then install the electrode in the port.
- Clean the CHLORIDE electrode and reinstall it in the appropriate port of the flow cell (refer to Section 9 for detailed procedure).
- Return the POTASSIUM electrode to the appropriate port of the flow cell. A dry POTASSIUM electrode requires soaking prior to installation. (Refer to Section 4 of the Diagnostics and Troubleshooting Guide.)

- Return the CALCIUM electrode to the appropriate port of the flow cell. A dry CALCIUM electrode requires soaking prior to installation. (Refer to Section 4 of the Diagnostics and Troubleshooting Guide.)
- 8. Reconnect the tubing to the CO₂ Alkaline Buffer, Flow Cell, and EIC solenoid valves.
- 9. Ensure solution grounds and all fluid lines are connected to the flow cell.
- 10. Reconnect the peri-pump tubing to the appropriate positions.
- Load reagents, except for CO₂ Acid (to prevent acid shock to the electrodes when priming), onto the system and reconnect the DI water wash solution lines.
- 12. Turn the REFERENCE peri-pump counterclockwise by hand until the Electrolyte Reference debubbler is one-half full (refer to Section 9 for detailed procedure).
- 13. Continue to turn the REFERENCE peri-pump until electrolyte reference reagent drips into the drain assembly. Ensure that there are no air bubbles in the reagent stream, especially in the back of the carbon bridge.
- 14. Clamp drain lines #22 and #23 between the flow cell and the drain assembly.
- 15. Make a mark on the REFERENCE peri-pump and turn the peri-pump counter-clockwise exactly two turns.
- 16. Leave the system undisturbed for ten minutes.
- 17. Remove the clamp from the drain lines and check to see if there is a sudden draining of electrolyte reference reagent into the drain assembly. If not, massage the tubing where it was clamped. If rapid draining doesn't occur, there may be a leak somewhere in the system. Call the Clinical Support Center, or your local Beckman office.
- 18. Load the CO₂ Acid reagent.
- 19. Replace the pressure bars on the E-Cam and C-Cam Pinch-Valve assemblies to operating position. Ensure bars are locked in place.
- 20. Reconnect peri-pump tubing to operating position.
- 21. Replace BUN, GLUCOSE, TOTAL PROTEIN or CALCIUM, and CREATININE stirrer bars to the proper modules.

NOTE

DO NOT INTERMIX STIRRER BARS

- 22. Remove BUN electrode from the electrode port. Remove quad-ring from face of electrode. Clean face of electrode and reinstall as instructed in Section 4 of the Troubleshooting and Diagnostics manual.
- 23. Remove GLUCOSE electrode from the electrode port. Charge and install electrode as instructed in Section 9 of this manual.
- 24. Load reagents onto the system.

CX4

- 1. Flush DI water as follows:
 - (a) Disconnect the DI water line from the back of the instrument. Place line into drain.
 - (b) Turn the external DI water valve leading to the instrument ON.
 - (c) Flush the DI water line for five (5) minutes.
 - (d) Turn the external DI water valve to the instrument OFF.
 - (e) Reconnect the line to the back of the instrument.
 - (f) Turn the external DI water valve leading to the instrument ON.
 - (g) Turn on the internal DI water valve in the hydropneumatic module ON.
- Check all wash bottles and float sensors for contamination. If contamination is noted, refer to the As Needed Maintenance procedure for Decontaminating the system, Section 9 of this manual.
- Place a new wash concentrate bottle on the system.
- Fill the probe rinse bottle with 750 mL DI water and add entire contents (250 mL) of concentrated probe rinse solution (P/N 443735) into the bottle.
- If the floppy disk shipping guard was inserted in Step 2, remove it.
- Press the AUX circuit breaker to the ON position. Press the MAIN circuit breaker to the ON position.
- 7. Prime the diluted wash bottles to fill as follows:
 - (a) From the MASTER Screen, press F4 SPECIAL FUNCTION.

- (b) Cursor and SELECT 1. Prime or type 1 ENTER.
- (c) Cursor and SELECT Fill Wash Bottles.
- (d) Press F1 START PRIME.
- 8. Observe the diluted wash bottles and determine which bottle the instrument fills first.
- Shut down the hydropneumatic system as follows:
 - (a) From the MASTER Screen, press F4 SPECIAL FUNCTION.
 - (b) Cursor and **SELECT** 6. Maintenance Procedures or type **6 ENTER**.
 - (c) Cursor and **SELECT** 4. Hydropneumatic Shutdown or type **4 ENTER**.
- Discard the contents of the first filled diluted wash bottle observed in Step 8, then replace on the instrument.
- Press ENTER to exit Hydropneumatic Shutdown and turn the hydropneumatic module back on
- Press F8 MAINT MENU to return to the MAIN-TENANCE Menu Screen.
- 13. Perform a cuvette wash as follows:
 - (a) Cursor and SELECT 2. Cuvette Wash, or type 2 ENTER.
 - (b) Repeat Step (a) two (2) more times.
- 14. Load CX4 reagents as required.
- Prime all CX3 Reagents/Modules 30 times as follows:
 - (a) From the MASTER Screen, press F4 SPECIAL FUNCTION.
 - (b) Cursor and **SELECT** 1. Prime, or type **1 ENTER**.
 - (c) Cursor and **SELECT** all CX3 Reagents/ Modules, or press **F3 PRIME ALL CX3**.
 - (d) Press F1 START PRIME to initiate priming.
 - (e) Type 30 ENTER.
- 16. Perform Daily through Two-Month Maintenance procedures on the CX3. (Refer to Section 9 of this manual.

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5.7 POWER LOSS TO THE HARD DRIVE

A power loss directly to the hard drive could result in a database corruption if the power loss occurs while the chemistry database is being accessed (written to). When the corruption occurs, a specific chemistry is marked for deletion from the chemistry database. The course of action is dependent upon whether a CX3 or CX4 chemistry has been affected. The corrective actions to return the system to normal operation are described below.

5.7.1 CX3 Chemistries

A corruption to the CX3 chemistry database may occur if direct power is lost during a Chemistry Update or during changes to units/precision or setpoints. Should this occur, a Fatal Note will be posted in the IDLE Screen, and the following steps should be taken:

- 1. From the IDLE screen, select F2 RESTORE.
- Restore parameters, using the Backup diskette, as outlined in Section 5.1.4.
- 3. When the Restore process is complete, reload all CX3 and CX4 reagents.
- 4. Recalibrate all CX3 and CX4 reagents.
- Check printouts of patient and control reports and repeat any samples which may have been lost.
- 6. Verify Host Parameters for proper set-up.
- QC results may be reviewed by loading the archived QC diskette, but these results may not be modified or combined with incoming QC results.

5.7.2 CX4 Chemistries

A corruption to the CX4 chemistry database may occur if direct power to the hard drive is lost during a Chemistry Update, reagent load, or during changes to units/precision, setpoints or slope and offset. Should this occur, the system will automatically reboot and a Recovery note may be displayed. The Recovery note will notify the operator of areas which may have been affected by the power loss. If power has been lost to the hard drive, the following steps should be taken whether or not a Recovery Note is displayed to return the system to normal operation:

- 1. Press **PRINT SCREEN** to print a hard copy of the Recovery Note (if displayed).
- Check the Chemistry Configuration Screen to see which chemistries are currently configured.

 If any CX4 chemistries have been deconfigured, refer to Section 5.1.5, "Database Recovery."

Note: If steps 3-6 are not performed and the chemistry database has been corrupted, QC control definitions may also be deleted resulting in corruptions to the QC database.

- 4. Follow the instructions outlined in Section 5.1.5 which direct the operator to load the last disk in the software installation diskette set (Chemistry Database diskette) through Chemistry Update.
- 5. After loading the diskette, check Chemistry Configuration to make sure that all desired chemistries are configured.
- Check the QC Define/Review Screen to make sure that the affected chemistries are still defined appropriately.
- QC results may be reviewed by loading the archived QC diskette, but these results may not be modified or combined with incoming QC results.

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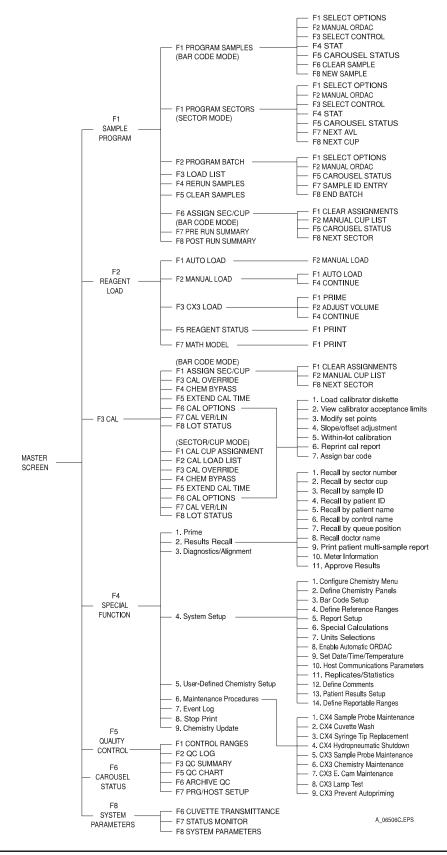
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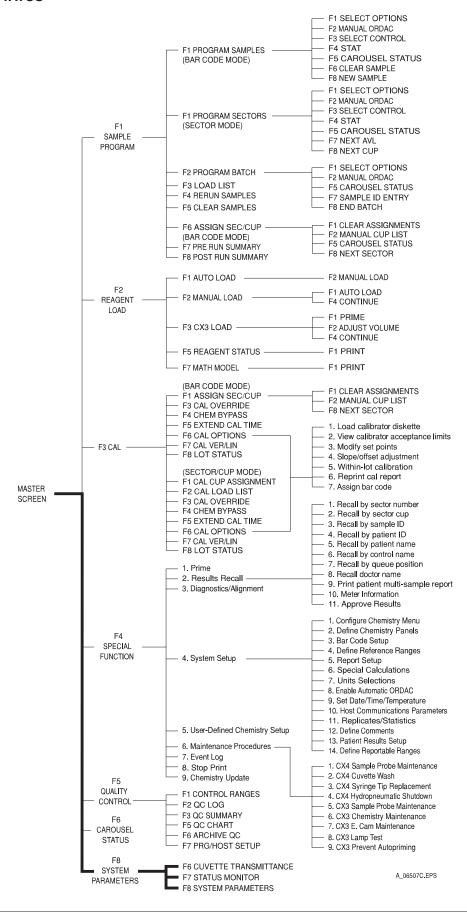
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Section 6 OPERATING INSTRUCTIONS



6.1 SYSTEM STATUS



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6.1.1 System Parameters

This feature provides a condensed reference to the following:

1. Current configuration of the instrument setup options

Configured chemistries Print Option

Assays/cup Special calculations

Statistics ORDAC enabled chemistries

Report formats enabled Selected temperature

Sector Reader

2. Calibrator lot numbers currently in memory as loaded by the calibrator diskette.

NOTE

For the Immuno Protein, Bilirubin, T4 and Digoxin Calibrators, this number is represented by the last two digits of the lot number followed by the calibrator level.

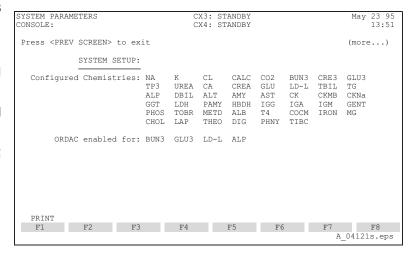
3. Cuvette water blank status

Water blank status lists the cuvettes which have exceeded the allowable limits at the <u>wavelength displayed</u>. These cuvettes will not be used for analysis until washed again, cleaned, or replaced and tested to within acceptable limits.

4. Version numbers for the various software components

Viewing the Current System Parameters

- From the MASTER Screen, press F8 SYSTEM PARAMETERS.
- 2. Press F8 SYSTEM PARAMETERS.
- Use the PAGE UP and PAGE DOWN keys to view additional information.
- 4. Press **F1 PRINT** for a hard copy of all parameters (refer to Figure 6-1).
- 5. Press PREV SCREEN or MASTER SCREEN to exit.



```
19 Jun 95
                                                                8:25:48
                                                                PAGE 1
                              SYNCHRON CX7 DELTA
                              SYSTEM PARAMETERS
                                SYSTEM SETUP
Configured Chemistries:
                         BUN3
                                                    ALB
                                             TP3
                              GLU3 CRE3
                                                           ALC
                                                                  ASO 
                                                                         BUN
                                CHOL
                         CA
                                       CREA
                                              CR-T
                                                    DBIL
                                                           GLU
                                                                  HDLC
                                                                         IRON
                         LAC
                                MG
                                       M-TP
                                              PHOS
                                                    P04
                                                           SAL
                                                                  T4
                                                                          TBIL
                         TG
                                TG-B
                                                     TRIG
                                       TIBC
                                              TP
                                                           TU
                                                                  URIC
                                                                         DIG
                                       PHNY THEO
                         GENT
                                PHNB
                                                     TOBR
                                                          CL
                                                                  002
                                                                         К
                         NA
                                CALC ALP ALPd
                                                     ALT
                                                           ALT-
                                                                  AMY
                                                                         AST
                                      CK CK-
LAP LDH
IGM TRF
                         AST-
                                CHE
                                      CK
                                                    CKMB
                                                           CKNa
                                                                  GGT
                                                                         GOT
                                                    LD-L
                         GPT
                                HBDH
                                                                  LIPA
                                                           I D-P
                                                                         CRP
                         IGA
                                19G
                                                    AMM
                                                           PAMY
                                                                  HAMB
    ORDAC Enabled For:
                         NONE
          Temperature:
                         37 deg C
           Assays/Cup:
                         1
           Statistics:
                         N/A
Patient Report Format:
                         Laboratory Format with ADC/ABS
Control Report Format:
                         Control Chart Report
         Print Option: Printouts Enabled
        Sector Reader:
                       Enabled
                       CUVETTE WATER BLANK STATUS
Cuvette(s) out of limits: NONE
                            SPECIAL CALCULATIONS
 OSMOLALITY (1) = (1.86 * NA) + (GLU3/18) + (BUN3/2.8) + 9
 OSMOLALITY (2) = (1.86 * NA) + (GLU/18) + (UREA) + 9
  ANION GAP (1) = NA - (CL + CO2)
  ANION GAP (2) = (NA + K) - (CL + CO2)
 A/G RATIO = ALB/(TP - ALB)
  INDIRECT BILL = TBIL - DBIL
 BUN/CREA RATIO = BUN/CREA
 UREA/CREA RATIO = UREA/CREA
 BUN/CR-T RATIO = BUN/CR-T
 UREA/CR-T RATIO = UREA/CR-T
 CREA CLEAR (1) = (U * V)/P * (1.73/A)
  CREA CLEAR (2) = (U * V)/P * (1.73/A)
 FREE THYROXINE = (T4 * TU)/34.2
                           CALIBRATOR INFORMATION
                                                                        6
  Cal Lot Numbers:
  Cal Standard 1
                    STD L1
  Cal Standard 2
                              STD L2
  Cal Standard 3
                                        STD L3
                    ALC CAL
  ALC
                                                                         A 05078C.EPS
```

Figure 6-1. System Parameters

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6.1.2 Status Monitor

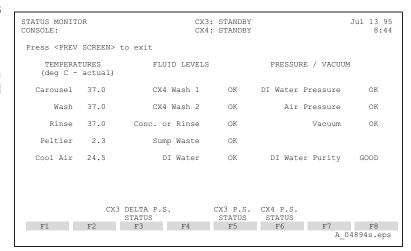
This feature, which is also available from the diagnostic screens, provides a summary of the system temperatures, fluid levels, pressures, and voltages on a real-time basis in that all parameters are updated approximately every three seconds. Any parameter which is outside the acceptable limits will display in red to alert the user to the problem area. (Refer to Paragraph 2.5 in Diagnostics and Troubleshooting Guide for corrective action if necessary.)

NOTE

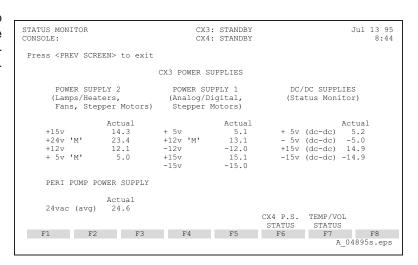
When accessing CX3 Power Supply Voltage Status in steps 4 or 5 below, be sure to select the status that corresponds with the instrument to avoid incorrect flagging of voltages. Operators with CX7 DELTA instruments should select **F3 CX3 DELTA P.S. STATUS**. Operators with CX7 instruments updated with DELTA software should select **F5 CX3 P.S. STATUS**.

Viewing the Real-Time Status Monitor

- From the MASTER Screen, press F8 SYSTEM PARAMETERS.
- 2. Press F7 STATUS MONITOR.
- The main STATUS MONITOR Screen displays system temperatures, fluid levels, pressures/vacuums, and DI water purity.



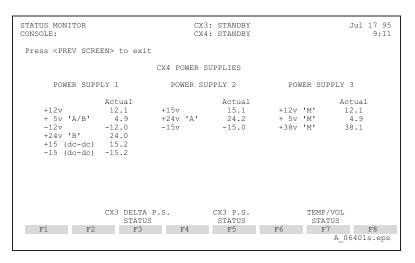
 Press F3 CX3 DELTA P.S. STATUS to view power supply voltages for the CX3 module of the CX7 DELTA. Values outside of tolerance limits are displayed in red.



 Press F5 CX3 P.S. STATUS to view power supply voltages for the CX3 module of the CX7. Values outside of tolerance limits are displayed in red.

STATUS MONITOR CONSOLE:			STANDBY STANDBY			Jul 13 95 8:47
Press <prev scre<="" td=""><td>EN> to exit</td><td></td><td></td><td></td><td></td><td></td></prev>	EN> to exit					
		CX3 POWER SU	PPLIES			
POWER SUPP	LY 4	POWER SUP	PLY 2	POWI	ER SUPPLY S	5
+15v -15v + 5v 'M' +24v 'M'	23.4	- 5v +12v	14.9	+13v POWI +17v	13 ER SUPPLY 3	
24vac (avg)						
				CX4 P.S. STATUS	STATUS	
F1 F2	F3	F4	F5	F6	F7	F8

- Press PREV SCREEN to return to the main SYSTEM PARAMETERS Screen, or F6 CX4 P.S. STATUS to view power supply voltages for the CX4 module. Values outside of tolerance limits are displayed in red.
- 7. Press **F7 TEMP/VOL STATUS** to return to the main MONITOR Screen.
- 8. Press PREV SCREEN to return to the SYSTEM PARAMETERS Screen or MASTER SCREEN to return to the MASTER Screen.



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6.1.3 Cuvette Transmittance

As a maintenance and troubleshooting aid this feature allows the operator to view the transmittance values for all 80 cuvettes at each of the 10 wavelengths available on the system. The system derives the data from transmittance values obtained during automatic water blank absorbance tests.

The information for 10 cuvettes is displayed on the screen. Use the **PAGE DOWN** and **PAGE UP** keys to move back and forth through all 80 cuvettes. A hard copy of these values can be obtained by pressing the **F1** key while in this feature.

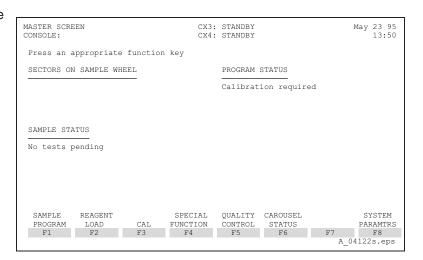
NOTE

Print out and save the cuvette transmittance report when the system is first installed and whenever maintenance or service is performed to the optics.

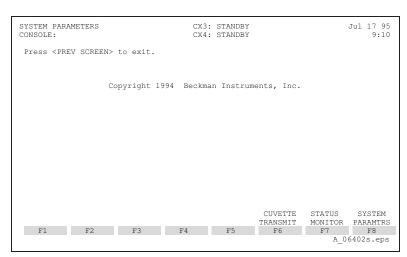
The current transmittance values are retained after the system shuts down but are lost when the system is reset, powered down, idle/resumed, or booted into diagnostics. Once absorbance values have been lost the displayed transmittance value will be 0 until a water blank absorbance test has been run by the system. The system automatically performs the water blank absorbance test while the system is running.

Viewing and Printing Cuvette Transmittance Data

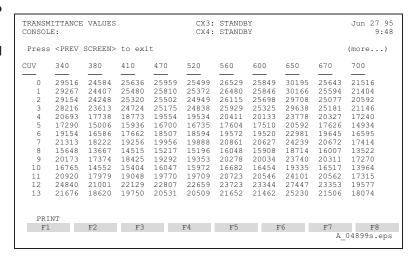
 From the MASTER Screen press the F8 SYSTEM PARAMETERS key.



2. Press the **F6 CUVETTE TRANSMIT** key to view the first 10 cuvettes.



- Press the PAGE DOWN or PAGE UP key to move through cuvettes 1-80.
- 4. Press **F1 PRINT** key to obtain a hard copy of all 80 cuvettes (Figure 6-2).



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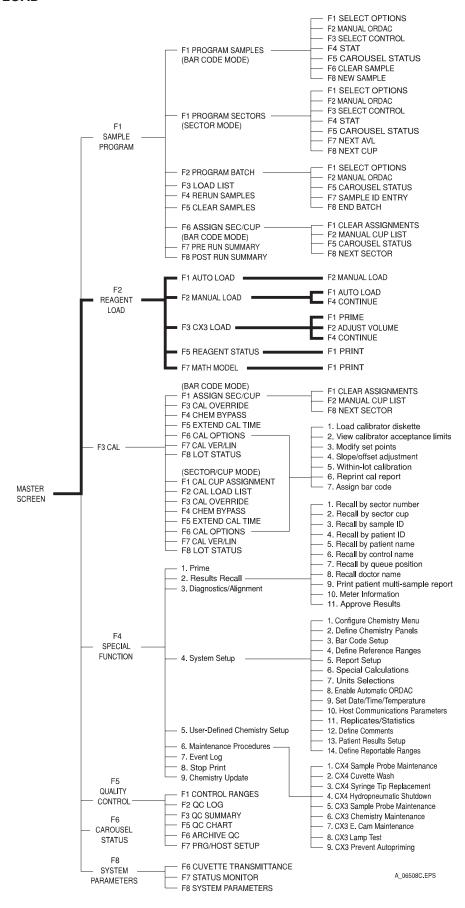
SYNCHRON CX7 DELTA

CUVETTE WATER BLK STATUS:

CUV	340	380	410	470	520	560	600	650	670	700
1	29601	24618	25670	25972	25483	26544	25911	30230	25646	21407
Ž	29204	24318	25388	25702	25245	26450	25875	30144	25545	21241
3	29094	24176	25235	25403	24820	26053	25689	29631	24995	20456
4	28314	23667	24778	25217	24848	25867	25301	29586	25114	21005
5	29204	24404	25497	25945	25537	26558	25888	30328	25776	21636
6	29003	24256	25344	25787	25367	26379	25713	30136	25613	21506
7	29550	24669	25761	26195	25753	26810	26120	30613	26017	21815
8	28945	24168	25239	25646	25214	26310	25661	30051	25524	21360
9	29184	24425	25520	25959	25510	26639	56005	30430	25836	21583
10	27987	23564	24706	25200	24833	25910	25361	29671	25200	21080
11	29269	24500	25605	26021	25568	26801	26155	30619	26000	21716
12	28805	24151	25281	25733	25321	26514	25925	30334	25745	21473
13	29328	24504	25601	25966	25492	26640	26047	30393	25768	21440
14	28726	24057	25189	25649	25238	26389	25811	30178	25608	21350
15	28928	24198	25284	25687	25276	26376	25716	30114	25590	21468
16	20929	18049	19162	19767	19631	20860	20817	24246	20627	17159
17	29256	24395	25477	25855	25405	26514	25893	30249	25664	21430
18	29194	24385	25472	25840	25391	26503	25878	30242	25667	21439
19	29117	24344	25434	25800	25359	26508	25898	30259	25681	21440
20	28500	23894	24986	25386	24974	26044	25452	29746	25258	21136
21	29306	24473	25552	25963	25536	26556	25878	30296	25747	21611
22	29566	24680	25746	26132	25674	26700	26016	30438	25851	21652
23	29211	24422	25496	25839	25368	26473	25856	30204	25637	21417
24	28903	24147	25225	25618	25188	26310	25709	30035	25494	21313
25	29078	24285	25365	25798	25371	26462	25817	30216	25667	21493
26	29034	24346	25441	25870	25452	26622	25939	30402	25840	21695
27	29250	24449	25533	25983	25560	26822	26125	30634	26039	21848
28	28581	23993	25107	25599	25229	26314	25667	30110	25606	21520
29	29099	24296	25371	25807	25385	26503	25827	30265	25722	21587.
30	29305	24510	25591	25979	25518	26651	25987	30414	25828	21619
31	28898	24159	25266	25588	25090	26269	25773	29987	25378	20985
32	29000	24294	25393	25793	25342	26462	25857	30233	25653	21402
33	29494	24612	25698	26073	25585	26741	26104	30508	25880	21569
34	29329	24473	25558	25937	25462	26617	26002	30372	25760	21459
35	29414	24569	25671	26081	25602	26717	26077	30504	25882	21580
36	28753	24099	25219	25670	25250	26289	25691	30070	25527	21319
37	27742	23302	24422	24936	24595	25728	25151	29501	25069	20986
38	27661	23256	24389	24946	24619	25792	25244	29620	25173	21063
39	29439	24614	25700	26085	25620	26794	26141	30591	25971	21709
40	28232	23658	24761	25294	24950	26008	25377	29799	25344	21289
								_		A_05079C.EPS

Figure 6-2. Cuvette Transmittance Printout

6.2 REAGENT LOAD



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Automatic and manual loading and unloading of CX4 reagent cartridges is allowed when the system is RUNNING, WAITING, or in STANDBY. CX3 reagents may only be loaded when the instrument is in STANDBY. If a CX4 reagent cartridge load is requested while the CX4 is RUNNING, the CX3 can continue running and the CX4 autoloader will continue loading samples. While the CX4 is RUNNING, the operator will be unable to remove a cartridge which has been programmed for calibration. Loading of calibrator diskettes is only allowed while the CX4 is IN STANDBY.

NOTE

If the system interrupts Reagent Load While Running with instrument errors, such as motion, printer, or host errors while the instrument status is "Pending Reagent Load," the operator should go to the Reagent Load Screen and press **F1 CANCEL LOAD**. It is important to Cancel Reagent Load before the pending load time counts down to zero to avoid the need to press **EMERGENCY STOP** at an inopportune time in testing.

6.2.1 Automatic Reagent Load

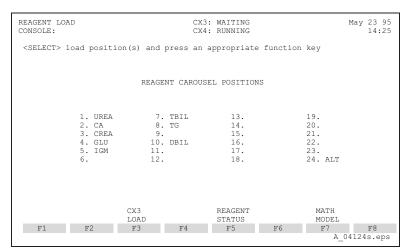
Automatic Reagent Load allows the operator to insert, replace, or remove reagent cartridges from any of the 24 positions on the CX4 reagent carousel using the bar code reader system. The reagent demographics, which include the test name, lot number, expiration date, and serial number, are encoded on the label and read by the bar code reader as the cartridges are loaded onto the carousel. These demographics make each cartridge unique, allowing the system to maintain an accurate inventory whether they are loaded on the reagent carousel or not.

NOTE

User-defined reagents may NOT be loaded or unloaded using this method.

- From the MASTER Screen, press F2 REAGENT LOAD.
- 2. The 24 positions on the CX4 reagent carousel are listed displaying all currently loaded reagent cartridges. Move cursor to an unoccupied position or a position occupied by a reagent to be removed and press SELECT to highlight position.

Repeat until all selections have been made. Positions may be de-selected by moving the cursor to the highlighted location and pressing **SELECT** again.



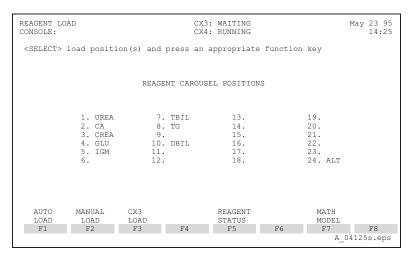
NOTE

If a cartridge is selected for removal and there are tests programmed for that cartridge, the operator will be allowed to remove the cartridge; however, the following message will appear: "Tests are Scheduled for this Chemistry".

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3. Press F1 AUTO LOAD.

4. If the system is RUNNING or WAIT-ING, the operator will be able to load cartridges after at least a 32 second delay. Since the system must complete all chemistry reactions waiting for a second reagent inject before loading cartridges, the operator may experience a delay longer than 32 seconds.



5. The Reagent Load Screen will display the time (in minutes and seconds) which remains until the cartridge can be loaded. This time is continually updated and displayed in the Reagent Load Screen only.

A request to load reagents may be cancelled by pressing the **F1 CANCEL LOAD** key.

The operator may exit the Reagent Load Screen during the reagent load pending state without cancelling the reagent load request.

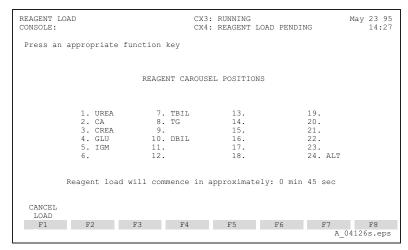
6. The operator will be allowed to load cartridges when the instrument status changes to "Loading Reagents" and the following message (accompanied by a single audible alarm) appears on any instrument screen:

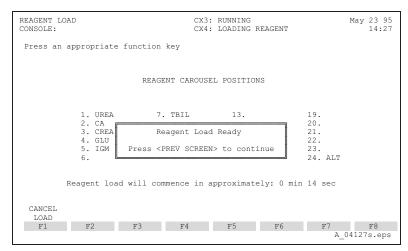
Reagent Load Ready
Press PREV SCREEN to Continue

Press **F2 REAGENT LOAD** if not already in this screen.

NOTE

When the instrument status changes to "Loading Reagents", the instrument will wait indefinitely if the operator does not load reagent cartridges.





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- 7. Remove all caps from the reagent cartridge; prepare reagent if required. Check each cartridge for bubbles at the top and mouth of each compartment; remove bubbles if present.
- The reagent carousel will rotate to the first position selected in ascending numeric order.
 - (a) To load a reagent cartridge:

When prompted on the screen, open the reagent door and load the desired reagent cartridge. To load, hold the cartridge by the wide end and slide it past the bar code reader into the carousel slot.

(b) To remove or replace a reagent cartridge:

When prompted on the screen, open the reagent door and remove the existing cartridge. To remove, grasp the cartridge from the top and bottom with the thumb and forefinger, lift slightly, and pull back.

NOTE

The reagent bar code reader will beep when reading the bar code label on the cartridge in both the backward and forward direction.

To properly load a cartridge the bar code label MUST be read in the forward direction. Verify that the screen has updated the display with the reagent name (before closing the reagent door). If the cartridge label is not read successfully, press F2 MANUAL LOAD and proceed with manual entry of the cartridge information (refer to paragraph 6.2.2). When information is entered. press **PREV** SCREEN to exit the window. Press F4 CONTINUE to continue loading manually. To return to Automatic Reagent Load, press F1 AUTO LOAD.

To properly remove a cartridge, the bar code label MUST be read in the backward direction.

 If this is a new lot of reagent for a multi-point chemistry, a message appears reminding the operator to verify that the correct math model is selected for this lot number.

Following completion of reagent load, press the **F7 MATH MODEL** key to verify that the math model selected for this reagent is correct. The math model is printed on the reagent cartridge label. For more information on math models, refer to Paragraph 6.2.5, Math-Model Selection.

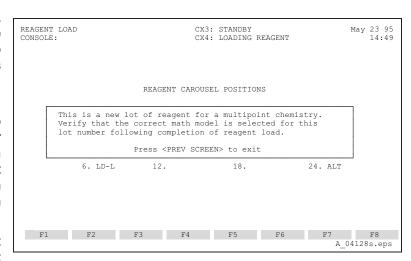
- 10. Close the reagent door. The reagent carousel will rotate to the next selected position. Repeat Steps 7 through 9 until all selected positions have been accessed.
- 11. When all reagents have been loaded, the reagent level of each newly loaded cartridge will be checked. The message "Checking levels" will be displayed in the CX4 status field until the entire process is complete. The accuracy of the level sense reading will be within approximately 10% of the actual volume of reagent in the cartridge.

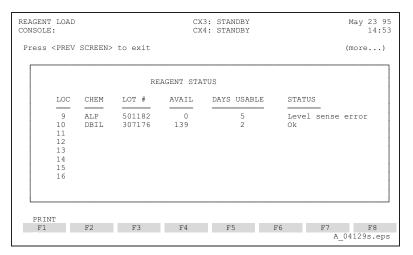
NOTE

Operator may exit the Reagent Load Screen during the reagent level check process. Keyboard input is also allowed in all screens.

12. If a level sense error occurs, the appropriate reagent will display a reagent status of "Pending Level Check" or "Level Sense Error".

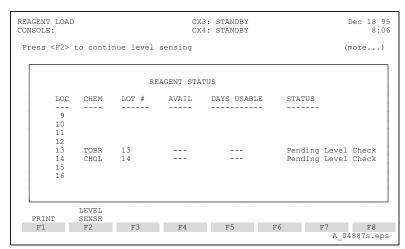
If a level sense error occurs, you must request a reagent load and remove and reload the cartridge.





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13. If a reagent has a status of pending level check, and you are in STANDBY ONLY, press F2 LEVEL SENSE to initiate level sensing for reagents with pending status.



6.2.2 Manual Reagent Load

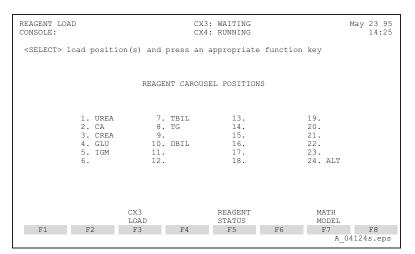
This option allows the operator to manually load, replace, or remove reagent cartridges in any of the 24 positions on the CX4 reagent carousel when: 1) a user-defined reagent cartridge is being used, 2) a reagent bar code label cannot be read properly, or 3) a malfunction of the reagent bar code reader occurs. Manual Reagent Load is allowed when the system is RUNNING, WAITING, or in STANDBY.

- 1. From the MASTER Screen, press **F2 REAGENT LOAD**.
- The 24 positions on the CX4 reagent carousel are listed displaying all currently loaded reagent cartridges. Move cursor to an unoccupied position or a position occupied by a reagent to be removed and press SELECT to highlight position.

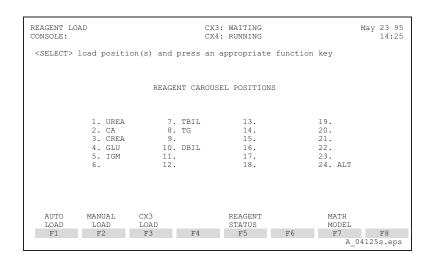
Repeat until all selections have been made. Positions may be de-selected by moving the cursor to the highlighted location and pressing **SELECT** again.

NOTE

If a cartridge is selected for removal and there are tests programmed for that cartridge the operator will be allowed to remove the cartridge; however, the following message will appear: "Tests are Scheduled for this Chemistry".



3. Press the F2 MANUAL LOAD key.

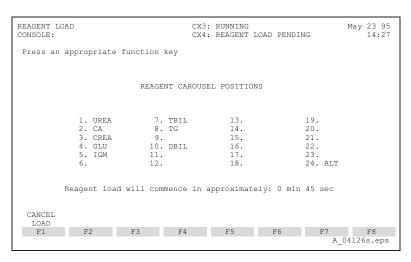


4. If the system is RUNNING or WAIT-ING, the operator will be able to load cartridges after at least a 32 second delay. Since the system must complete all chemistry reactions waiting for a second reagent inject before loading cartridges, the operator may experience a delay longer than 32 seconds.

The Reagent Load Screen will display the time (in minutes and seconds) which remains until the cartridge can be loaded. This time is continually updated and displayed in the Reagent Load Screen only.

A request to load reagents may be cancelled by pressing the **F1 CANCEL LOAD** key.

Operator may exit the Reagent Load Screen during the reagent load pending state without cancelling the reagent load request.



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5. Operator will be allowed to load cartridges when the instrument status changes to "Loading reagents" and the following message (accompanied by a single audible alarm) appears on any instrument screen:

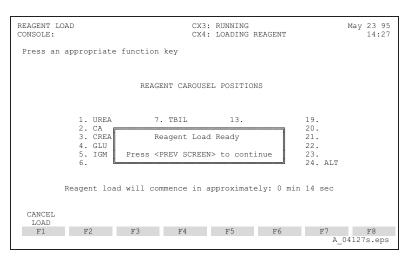
Reagent Load Ready
Press PREV SCREEN to Continue

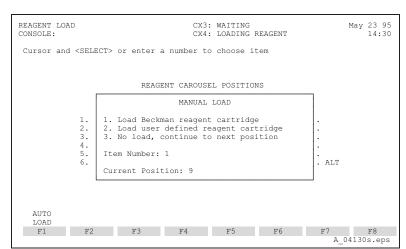
Press **F2 REAGENT LOAD** if not already in this screen.

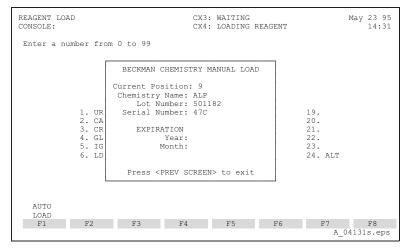
NOTE

When the instrument status changes to "Loading Reagents", the instrument will wait indefinitely if the operator does not load reagent cartridges.

- The reagent carousel will rotate to the first position selected in numeric order. Three options are displayed in a window:
 - (a) If the cartridge to be loaded is a
 Beckman reagent, cursor and
 SELECT 1. Load Beckman
 reagent cartridge or type 1
 ENTER. Proceed to Step 7.
 - (b) If the cartridge to be loaded is a user-defined cartridge, cursor and SELECT 2. Load user defined reagent cartridge or type 2 ENTER. Proceed to Step 8.
 - (c) If no reagent cartridge is to be loaded, cursor and SELECT 3. No load, continue to next position, or type 3 ENTER.
- 7. If option 1 was selected, enter the reagent name, lot number, serial number and expiration date listed on the reagent label. All fields must be entered for proper tracking of reagent information. Press PREV SCREEN when done.







For example:

ALP

Lot Number: 501182 Serial Number: 47C Expiration Date: 96

06

NOTE

Entries for lot number and serial number are case dependent. Enter cartridge name exactly as printed on the label. Enter serial number. When entering the lot number, do not use the leading alpha character. For example, if the lot number is C501182, enter 501182.

8. If option 2 was selected, type the test name and press **ENTER**.

NOTE

The test name must be identical to the name defined in User-Defined Chemistry Setup, Paragraph 8.2.

 Remove caps from reagent cartridge; prepare reagent if required. Check each cartridge for bubbles at the top and mouth of each compartment; remove bubbles if present.

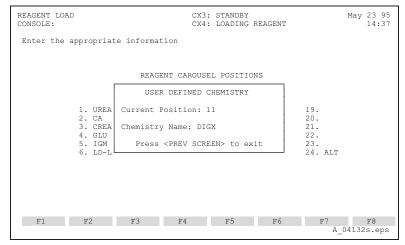
10.

(a) To load a reagent cartridge:

When prompted on the screen, open the reagent door and load the desired reagent cartridge. To load, hold the cartridge by the wide end and slide it past the bar code reader into the carousel slot.

(b) To remove or replace a reagent cartridge:

When prompted on the screen, open the reagent door and remove the existing cartridge. To remove, grasp the cartridge from the top and bottom with the thumb and forefinger, lift slightly, and pull back.



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 Close the reagent door and press F4 CONTINUE.

If this is a new lot of reagent for a multi-point chemistry, a message appears reminding the operator to verify that the correct math model is selected for this lot number.

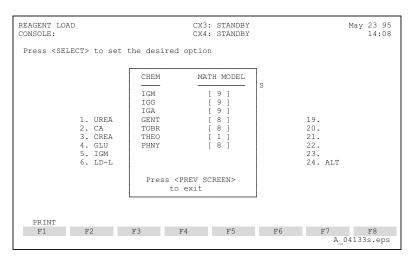
- 12. Following completion of reagent load, press the **F7 MATH MODEL** key to verify that the math model selected for this reagent is correct. The math model is printed on the reagent cartridge label. For more information on math models, refer to Paragraph 6.2.5, Math Model Selection.
- The carousel will rotate to the next selected position. Repeat Steps 6 through 12 until all positions have been accessed.
- 14. When all reagent cartridges have been loaded, the reagent level of each newly loaded cartridge will be checked. The message "Checking levels" will be displayed in the CX4 Status field until the entire process is complete. If no cartridge is loaded, no reagent level check will occur.

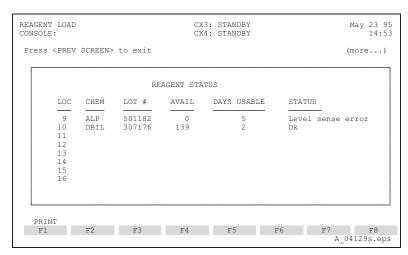
NOTE

Operator may exit the Reagent Load Screen during the reagent level check process. Keyboard input is also allowed in all screens.

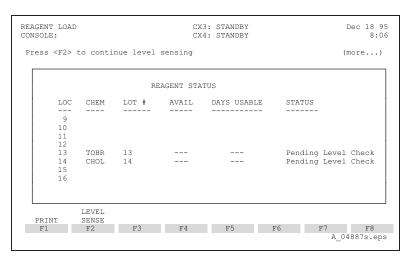
15. If a level sense error occurs, the appropriate reagent will display a reagent status of "Pending Level Check" or "Level Sense Error".

If a level sense error occurs, you must request a reagent load and remove and reload the cartridge.





16. If a reagent has a status of pending level check, and you are in STANDBY ONLY, press F2 LEVEL SENSE to initiate level sensing for reagents with pending status.



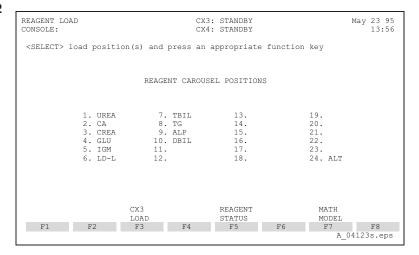
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6.2.3 CX3 Reagent Load (for CX7 Users Only)

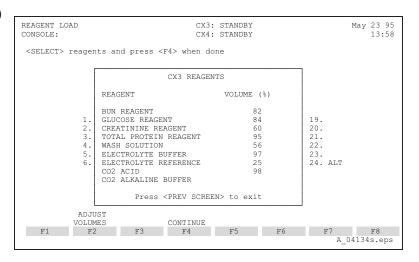
The CX3 chemistries use a different reagent system than the photometric chemistries. Reagents are stored in 2-L, 1-L or 500-mL bottles (wash solution is stored in a 10L container). These include Electrolyte Buffer, CO₂ Acid, Electrolyte Reference, and CO₂ Alkaline reagent, CX3 Glucose reagent, CX3 BUN reagent, CX3 Creatinine reagent and CX3 Calcium (Cup) or Total Protein reagent and wash solution. Although there is no level-sensing mechanism associated with the CX3 reagents, tracking of reagent level is automatically done on a percent volume basis once the initial volume is set when loaded.

Loading CX3 Reagents

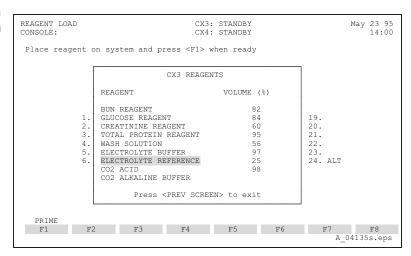
- 1. From the MASTER Screen, press **F2 REAGENT LOAD**.
- 2. Press F3 CX3 LOAD.



- Move cursor to the desired reagent(s) and press SELECT to mark.
- 4. Press F4 CONTINUE.



Place all selected reagent bottles on the system. Press F1 PRIME when done.



The new bottles of reagent will be sufficiently primed to refresh all the lines.
 The message "Loading" will be displayed in the CX3 Status field until reagent load is completed.

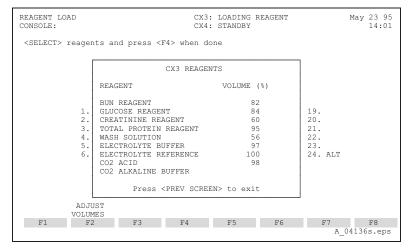
NOTE

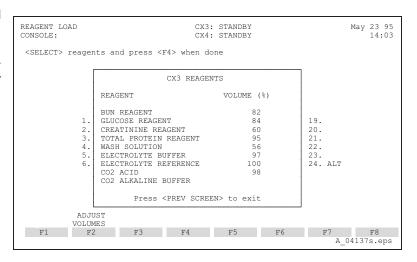
When a CX3 load is performed from a dry state, additional prime cycles may be required for adequate filling of the reagent lines.

7. The reagent volume (%) is assumed to represent a full bottle (that is, 100%). If a full bottle was loaded, press **PREV SCREEN**. If a partial bottle was loaded, adjust the volume by pressing **F2 ADJUST VOLUME**.

NOTE

CO₂ Alkaline Reagent is recycled and therefore never consumed. It is recommended, however, that it be replaced monthly with fresh reagent (refer to Paragraph 9.4.8).





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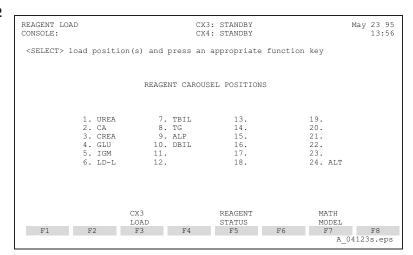
- 8. If the volume is not 100%, enter the approximate percentage of remaining reagent to ensure proper tracking. Arrows on the reagent bottle labels indicate 75%, 50% and 25% of full levels. Press **F4 CONTINUE**.
- 9. Press **PREV SCREEN** to exit the volume entry window.
- 10. Press **PREV SCREEN** or **MASTER SCREEN** to exit Reagent Load.

6.2.4 Reagent Status Information

Each Beckman cartridge is serialized so that information regarding reagent consumption and viability is stored in memory for the life of the reagent on and off the system. This feature allows the operator to view the status of the reagent cartridges loaded on the system. (Refer to Appendix C for comprehensive status matrix.)

Viewing Reagent Status

- 1. From the MASTER Screen, press **F2 REAGENT LOAD**.
- 2. Press F5 REAGENT STATUS.



Current status of all on-board cartridge reagents (CX4) is displayed first. Press the PAGE UP or PAGE DOWN key to view additional information. Status information for cartridge reagents includes the following:

LOC position on the reagent carousel

CHEM name of the reagent

LOT # reagent lot number

AVAIL number of tests remaining

NOTE

The number displayed may exceed the number indicated on the cartridge due to overfilling.

DAYS USABLE countdown of

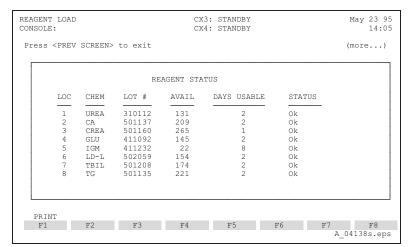
stability since first loaded on the

system

STATUS indication of any

error conditions (refer to Appendix C for an explanation of the status

messages)

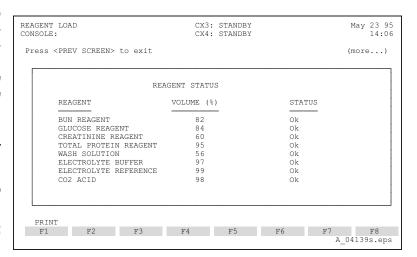


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NOTE

For User Defined Chemistry reagents on board, only LOC, Chem, Avail, and Status information is stored.

- 4. For CX7 users only, the status of the electrolyte reagents and stat chemistry reagents (CX3 module) is displayed following the CX4 reagents. CX3 status provides the status of the reagent as well as the % volume remaining.
- To obtain a hard copy of the status, press F1 PRINT from the REAGENT STATUS Screen.
- Press the PREV SCREEN key to close window.
- Press PREV SCREEN or MASTER SCREEN to exit.



6.2.4.1 Real-Time Cartridge Status

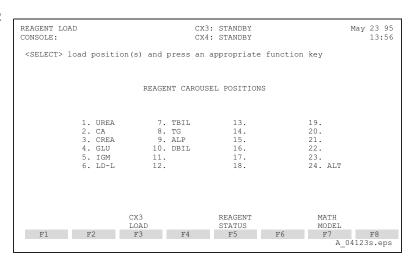
Operators are notified by a real-time message display when the number of tests remaining in a reagent cartridge is 10 tests, 5 tests, and 0 (zero) tests. The reagent name and reagent carousel position are included in the message.

This feature allows the operator to program and load control samples immediately before and/or after a new cartridge is placed in use for a specific chemistry.

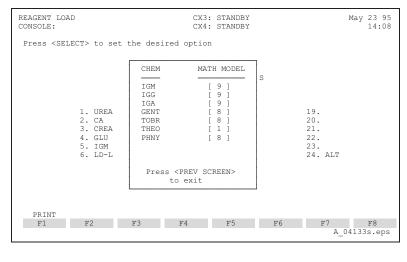
6.2.5 Math Model

The Math Model function allows the operator to select one of five calibration formulas for a given multipoint chemistry. The calibration formulas are referred to as math models on the system. Available math models are 1, 2, 3, 8 and 9. The appropriate math model for a given multipoint chemistry is noted on the cartridge label of each Beckman reagent cartridge.

- 1. From the MASTER Screen, press **F2 REAGENT LOAD**.
- From the REAGENT LOAD Screen, press F7 MATH MODEL.



- Multipoint chemistries are listed with default Math Models (refer to Table 6-1). Use the Up/Down arrow keys or ENTER to move from one chemistry to another.
- To change a Math Model, move the cursor to the desired multipoint chemistry and press SELECT to toggle through the five math model selections.
- 5. Use **F1 PRINT** to generate a hard copy of the multipoint chemistries and their respective math models.
- When selections are complete, press PREV SCREEN. A message is displayed to inform the operator of any new calibration requirements due to Math Model changes.
- 7. To save newly selected Math Models and exit to the REAGENT LOAD Screen, type Y and press ENTER. Typing N does not save the newly selected Math Models.
- Press PREV SCREEN or MASTER SCREEN to return to the MASTER Screen.



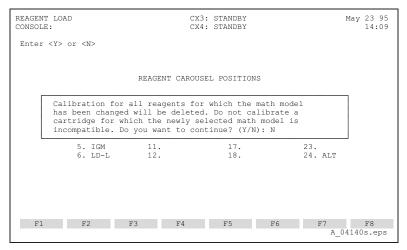
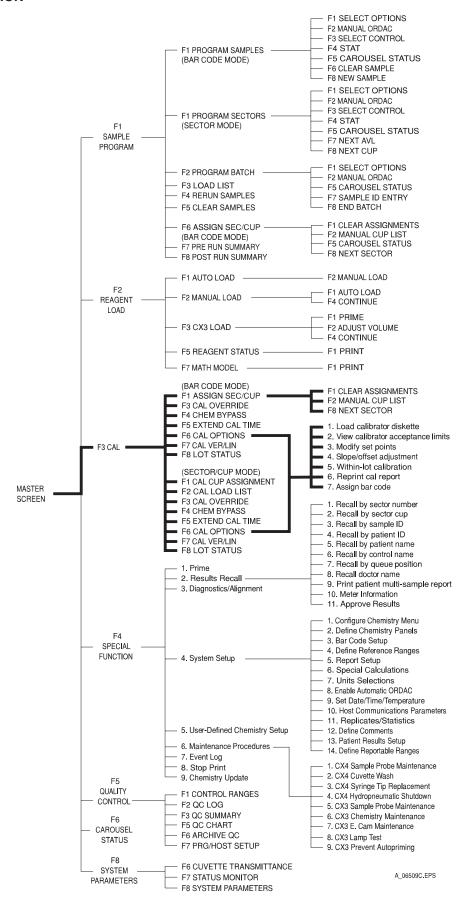


Table 6-1. Math Models

Chemistry	Math Model
GENT	8
PHNB	1
PHNY	8
THEO	1
TOBR	8
CRP	1
IgA	9
IgG	9
IgM	9
TRF	9

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6.3.1 Chemistry and Drug Calibration

Most chemistries analyzed on this system require calibration to standardize the analysis of samples to existing conditions. A calibration is required whenever a new reagent lot is used, a new reagent cartridge is used (except when within-lot calibration applies), at recommended calibration frequency intervals (Table 6-2), when indicated by control results, or after specified maintenance and diagnostics procedures. Calibration of electrolytes (Na, K, Cl, CALC and CO₂) is required after rebooting the system.

NOTE

CX3 chemistries must be calibrated prior to pickup of patient samples or controls. Samples for CX4 chemistries may be aspirated before calibration is successfully completed. User Defined chemistries must have a successful calibration completed before the instrument will aspirate patient samples or controls.

Table 6-2. Individual and Within-lot Calibration Frequencies

Chemistry	Cal Frequency	Within-lot Cal Frequency
NA, K, CL, CO _{2,} CA3, CALC (ISE) BUN3, URE3, GLU3, CRE3	24 hours	N/A
TP3	7 days	N/A
DIG	3 days	N/A
BUN,UREA	24 hours	30 days
T4, TU	24 hours	N/A
CREA, CR-T	7 days	30 days
ALC	4 days	N/A
AMM, LIPA, AST-, ALT-	5 days	N/A
TP, MG	7 days	90 days
AMPH, BARB, BENZ, COCM, LAC, METD, OP, PCP, SAL, THC, THC5	7days	N/A
CA	14 days	30 days
CAR, GEN, PHE, PHY, THE, TOB, VPA	14 days	42 days
GLU, URIC, CHOL, ALB, TBIL, DBIL, HDLc, M-TP, TG, TG-B	14 days	90 days
PHOS, PO4	14 days	60 days
THEO, GENT, TOBR, PHNY, PHNB, IgG, IgM, IgA, TRF, FE, IBCT, IRON, TIBC, TRIG, ASO, METQ, PROX, THC2	14 days	N/A
CK-	21 days	N/A
ASO-, CRP, RF	30 days	42 days

Individual laboratory variables, such as frequency of maintenance, maintenance technique, sample type, and workload, can generate conditions where the stability of the calibration can be longer or shorter than the above recommended times.

CAUTION

Changes in ambient temperature and environmental conditions may result in an 'excessive reference drift' message, indicating that the electrolyte chemistries must be recalibrated.

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Table 6-3. Calibrators

Chem	Calibrator	# of Cal.	Cal. Disk	Math Model	Open Stability	Open Temp °C	Cal Prep.	Cal. Kit P/N
ALB, BUN, CA, CHOL, CREA, GLU, LAC, MG, PHOS, PO4, TP, TG, TG-B, UREA, URIC	CX Multi™ Calibrator	1	Y	N/A	20 Days	2 - 8	None	442600
CR-T	CX Multi™ Calibrator*	2	Υ	N/A	20 Days	2 - 8	None	442600
NA, K, CL, CO ₂ , CALC (ISE), BUN3, URE3, CA3, CREA3, GLU3	Std. 1	1	N	N/A	30 Days	RT	None	465908
NA, K, CL, CALC (ISE), BUN3, URE3, CA3, CREA3, GLU3	Std. 2	1	N	N/A	30 Days	RT	None	465909
NA, K, CL, CO ₂	Std. 3	1	N	N/A	30 Days	RT	None	465910
TP3	Protein Calibrator	2	Υ	n/a	60 Days	2 - 8	None	450202
TBIL	Bilirubin Calibrator	1	Υ	N/A	24 Hours	2 - 8	None	442605
DBIL	Bilirubin Calibrator**	2	Υ	N/A	24 Hours	2 - 8	None	442605
CAR, PHE, PHY, THE, VPA	SYNCHRON Drug Cal 1	6	N	8	Exp. Date	2-8	None	469600
GEN	SYNCHRON Drug Cal 3	6	N	8	Exp. Date	2-8	None	469650
ТОВ	SYNCHRON Drug Cal 4	6	N	8	Exp. Date	2-8	None	469920
GENT	GENT Calibrator	6	Ν	8	60 Days	2 - 8	None	442851
TOBR	TOBR Calibrator	6	Ν	8	60 Days	2 - 8	None	442876
THEO	THEO Calibrator	6	Ν	1	60 Days	2 - 8	Recon.	442850
PHNY, PHNB	PHNY/PHNB Calibrator	6	Ν	8	60 Days	2 - 8	None	442862
IGA, IGG, IGM, TRF	Immunoprotein***	5	Υ	9	60 Days	2 - 8	None	442840
HDLC	HDLC Calibrator	1	Υ	N/A	60 Days	2 - 8	None	445950
IRON, TIBC, FE, IBCT	IRON/TIBC Calibrator	2	Ν	N/A	Exp. Date	2 - 26	None	442772
ASO	CX™ ASO Calibrator	1	Ν	N/A	15 Days	2 - 8	Recon.	450110
ASO-	CAL 5 Plus	1	Υ	N/A	Exp. Date	2-8	None	469965
CRP	CX™ CRP Cal	5	Υ	1	60 Days	2 - 8	None	445915
RF	CX™ RF Cal	6	Υ	9	60 Days	2 - 8	None	471225
M-TP	Microprotein Calibrator.	1	Υ	N/A	60 Days	2 - 8	None	445930
AST-, ALT-, CK-	SYNCHRON Enzyme Validator	2	Υ	N/A	60 Days	-15 to -20	None	441350
DIG	DIG Calibrator	2	Υ	N/A	30 Days	2 - 8	Recon.	Incl. w/ Rgt. Kit
AMM	AMM Calibrator	2	N	N/A	60 Days	2 - 8	None	Incl. w/ Rgt. Kit
ALC	Alcohol Calibrator	1	N	N/A	7 Days	2 - 8	None	Incl. w/ Rgt. Kit
SAL	SAL Calibrator*	2	N	N/A	30 Days	2 - 8	None	Incl. w/ Rgt. Kit
TU	TU Calibrator	2	Υ	N/A	21 Days	2 - 8	Recon.	Incl. w/ Rgt. Kit
T4	T4 Calibrator	2	Υ	N/A	30 Days	2 - 8	Recon.	Incl. w/ Rgt. Kit

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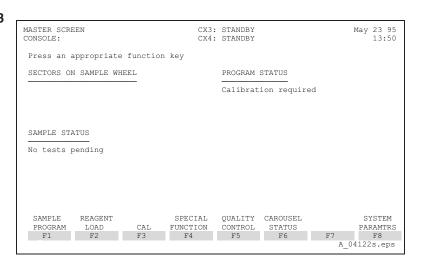
Table 6-3. Calibrators (Continued)

Chem	Calibrator	# of Cal.	Cal. Disk	Math Model	Open Stability	Open Temp °C	Cal Prep.	Cal. Kit P/N
LIPA	LIPA Calibrator*	2	Υ	N/A	45 Days	2 - 8	Recon.	Incl. w/ Rgt. Kit
AMPH, COCM, OP, PCP	DAT Neg. Urine Cal. DAT Low Urine Cal. I DAT High Urine Cal. I	3	N N N	N/A N/A N/A	60 Days 60 Days 60 Days	2 - 8 2 - 8 2 - 8	None None None	445803 445801 445802
BARB, BENZ, METD, METQ, PROX	DAT Neg. Urine Cal. DAT Low Urine Cal. II DAT High Urine Cal. II	3	N N N	N/A N/A N/A	60 Days 60 Days 60 Days	2 - 8 2 - 8 2 - 8	None None None	445803 445806 445807
THC5	DAT Neg. Urine Cal. 50 ng/mL THC Urine Cal. 100 ng/mL THC Urine Cal.	3	N N N	N/A N/A N/A	60 Days 60 Days 60 Days	2 - 8 2 - 8 2 - 8	None None None	445803 445809 445811
THC2	DAT Neg. Urine Cal. 20 ng/mL THC Urine Cal. 50 ng/mL THC Urine Cal.	3	N N N	N/A N/A N/A	60 Days 60 Days 60 Days	2-8 2-8 2-8	None None None	445803 464390 445809
THC	DAT Neg. Urine Cal. 100 ng/mL THC Urine Cal. 200 ng/mL THC Urine Cal.	3	N N N	N/A N/A N/A	60 Days 60 Days 60 Days	2 - 8 2 - 8 2 - 8	None None None	445803 445811 445814

^{*} Level 1 is user-supplied physiological saline.

6.3.1.1 Requesting a Calibration in Sector/Cup Mode

 From the MASTER Screen, press F3 CAL.



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^{**} Level 2 is user-supplied physiological saline.

^{***} Immunoprotein analysis requires a multi-point calibration curve generated by assaying a series of 5 standards. All standards, controls, and patient samples must be manually diluted according to the Chemistry Information sheets (contained in *Chemistry Information Manual*) prior to being assayed. Therefore, immunoprotein assay requests cannot be intermixed with standard chemistry or drug requests. The calibrator contains all the immunoproteins.

2. Review the status to determine which chemistries need calibration (Table 6-4).

NOTE

CX3 chemistries, in reagent positions 25-32 (33 with CALC ISE), are displayed first due to their calibration frequency. Use PAGE DOWN or PAGE UP to additional chemistries view available for calibration. Only chemistries with on-board reagent are displayed. Most enzymes are electronically calibrated and cannot be requested for calibration by the operator. (Example of exception: ALT-).

LIBRAT NSOLE:				: STANDBY : STANDBY			Jun 27 9:5
SELECT	r> chemis	stries for c	alibration. H	Press <f1></f1>	when done		(more
LOC	CHEM	RGT LOT #	TIME LEFT		STATU	S	
25	BUN3	N/A		* Cal	libration	required	
26	GLU3	N/A		* Ca.	libration	required	
27	CRE3	N/A		* Ca.	libration	required	
28	TP3	N/A		* Ca.	libration	required	
29	NA	N/A		* Ca.	libration	overridde	n
30	K	N/A		* Ca.	libration	required	
31	CL	N/A		* Ca:	libration	required	
32	CO2	N/A		* Ca.	libration	required	
33	CALC	N/A		* Ca:	libration	required	
1	ALB	311223	- 01:02:43	3 * Ca:	libration	timed out	
2	ALT	502161		N/A	A		
3	PHOS	408025	- 01:02:43		libration	timed out	
4	CHOL	401169	- 01:02:41	l * Cai	libration	timed out	
5	ALB	404234	00:02:42	2 Cal	librated		
CAL C	JP CAL I	LOAD CAL	CHEM	EXTEND	CAL	CAL VER/	LOT
SSGNM	VT LIS	ST OVERRI	DE BYPASS	CAL TIME	OPTIONS	LIN	STATUS
F1	F2	F3	F4	F5	F6	F7	F8

Table 6-4. Calibration Status, Sector Mode (Refer to Appendix D for a comprehensive status matrix.)

STATUS	DESCRIPTION				
Requested	Indicates that chemistries have been selected for calibration, but have not been assigned a sector/cup position.				
Requested and Assigned	Indicates that calibration is pending and cups have been assigned for calibration.				
Calibrated	Indicates that the chemistry has been calibrated and has not exceeded its calibration time period.				
Calibration Required	Appears when a new cartridge is loaded, a user-defined catridge is loaded, the system temperature has been reset, or non-overrideable calibration failure has occurred. Also appear when an ISE instrument reboot has taken place.				
Cal Overridden	Operator-initiated; results are based on the failed calibration.				
Chem Bypassed	Operator-initiated; allows analysis to proceed on all other chem istries without having to deprogram the bypassed chemistry. A bypassed chemistry must be recalibrated to run. (Refer to para graph 6.3.3 to Undo Bypass of Non-calibrated Chemistries).				
Failed Calibration	Indicates that calibrator values for a chemistry have exceeded calibration acceptance limits.				
Cal Timed Out	Time from previous calibration has exceeded the recommended calibration period.				
Cal Time Extended	Operator-initiated; indicates that the recommended calibration period has been extended. The chemistry must have a valid current calibration to be extended.				
Within Lot Pending	Indicates calibration has been requested for another cartridge with the same lot number. Applies only to chemistries with within-lot capability. (Refer to Paragraph 6.3.9)				

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 Move cursor to the chemistries or drugs to be calibrated and press SELECT. Use the PAGE keys to view additional information.

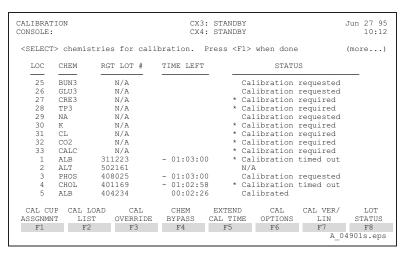
NOTE

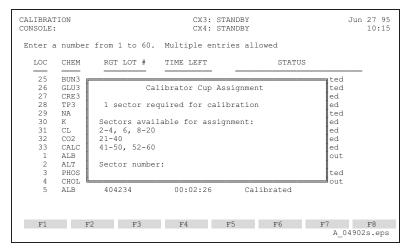
A calibration request may be deselected by pressing the **SELECT** key at the specific location. CX4 chemistries currently selected and programmed for calibration may be deselected only if the calibration is not yet in progress; CX3 calibration requests may be selected or de-selected only when the CX3 is in Standby.

4. Press F1 CALCUP ASSIGNMENT. Based on the requested calibrations, the system determines the minimum number of sectors required for calibrator cup assignment. Using the list of available sectors, type the required sector numbers and press ENTER. Use the comma (,) or dash (-) keys to enter multiple sectors. The cups are automatically assigned once the sectors have been designated.

NOTE

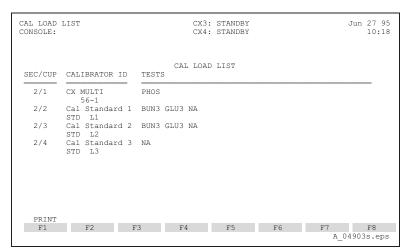
If there are insufficient available sectors for calibrator cup assignment, sectors must be cleared in Sample Programming (Paragraph 6.4) prior to completing this procedure. All levels of a calibrator must reside on the same sector. Calibrators and patient or control samples cannot be programmed on the same sector.





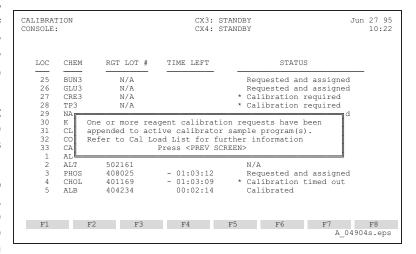
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A list of cups assigned to the appropriate calibrators may be viewed by pressing F2 CAL LOAD LIST. If desired, a printout of the Cal Load List may be generated by pressing F1 PRINT (refer to Figure 6-3).



Calibration selections will be automatically matched with active calibration programs if they exist. If a match is made, the newly selected calibration request is automatically appended to the appropriate program. Three such "append" possibilities exist:

- If the auto append feature does not apply to the chemistry selected, the Cal Cup Assignment window is displayed.
- If the auto append process applies to only a portion of the selections, a window informs the operator that one or more calibration requests have been appended to active calibration sample programs. Pressing PREV SCREEN activates the Cal Cup Assignment window for making the necessary cup assignments.
- If all of the chemistries requested for calibration are satisfied by auto append, a message is displayed to inform the operator. The Cal Cup Assignment window is not displayed in this case.



				27 Jun 95 10:28:03 PAGE 1
		CX7 DELTA CAL LOAD L	IST	**
SEC/CUP	CALIBRATOR ID	CAL LOT ID OR CAL LEVEL LOT ID	TESTS	
2/1	CX MULTI	56 1	PHOS	
2/2 -	Cal Standard 1	STD L1	BUN3, GLU3,	NA
273	Cal Standard 2	STD L2	BUN3, GLU3,	NA
2/4	Cal Standard 3	STD L3	NA	A_05124C.EPS

Figure 6-3. Cal Load List

- 6. Place fresh calibrator(s) in the appropriate cup positions and sector(s). Some calibrators (e.g. immunoproteins) require dilution before use. Manually dilute each calibrator as required, according to instructions on the appropriate Chemistry Information Sheet.
- 7. Load the sectors onto the system (refer to Paragraph 5.5 for instructions on using the autoloader).
- 8. Press PREV SCREEN or MASTER SCREEN to exit.
- 9. Press **START** to start the system when ready.

NOTE

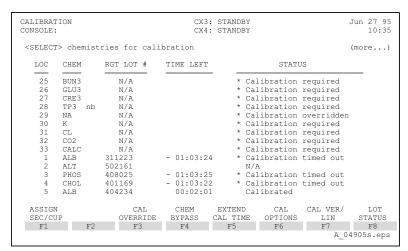
Calibration reports for a given CX4 calibrator do not print out until all calibrations are complete for each chemistry requested, unlike sample and control results, which print out on a cup-by-cup basis. CX3 calibration reports print out when all requested calibrations are complete (TP3 will print separately).

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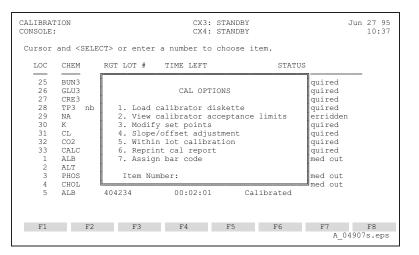
6.3.1.2 Assigning Bar Code IDs to Calibrators

In the bar code mode, bar codes are assigned to calibrators (all levels), then chemistries are requested for calibration.

- 1. From the MASTER SCREEN press **F3 CAL**.
- When the calibration status is displayed, check to see if the reagent pack to be calibrated has an assigned bar code ID. Reagent packs without assignments are designated with the letters "nb" after the chemistry name.



- To assign a barcode, press F6 CAL OPTIONS.
- From the Cal Options menu, cursor and SELECT 7. Assign Bar Code, or type 7 ENTER. These Bar Codes may be used repeatedly.



WARNING

When creating Calibrator Bar Code IDs, use a format that distinctly differs from that used for sample IDs. This will prevent the reporting of erroneous results due to Calibrators being run as Patient Samples, or Patient Samples being run as Calibrators.

Examples:

Calibrator Bar Code ID: CX MULTI

Sample Bar Code ID: 0000001

5. Locate the appropriate calibrator(s) for the reagents to be calibrated. Enter the bar code to be used (up to 11 alphanumeric characters). Press ENTER after each bar code entry. Use PAGE UP/PAGE DOWN to access additional calibrator information. Press F1 PRINT to obtain a hard copy of the assigned calibrator bar code. ID's.

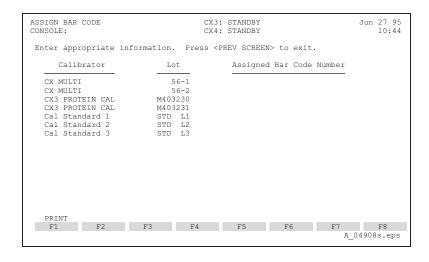
NOTE

Invalid characters for calibrator bar code ID include *, ?, \$, space, comma and semi-colon. Alpha characters must be entered in upper case when using code 39 (Refer to Appendix H).

 Press PREV SCREEN to return to the CALIBRATION Screen. The nb designation is removed from the reagent packs whose calibrator has an assigned bar code ID.

NOTE

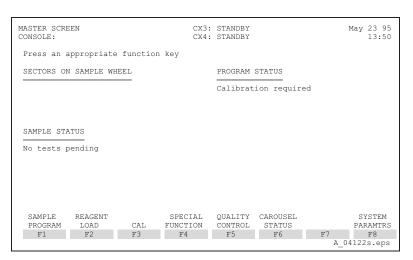
UDR Calibrator Bar Code IDS will not display in the Bar Code Assignment screen if the UDR has been deconfigured or the cartridge has been removed from the reagent carousel. However, the Bar Code ID will remain assigned until cleared by the operator.



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6.3.1.3 Requesting a Calibration in Bar Code Mode

1. From the MASTER SCREEN press F3 CAL.



2. Review the status (Refer to Table 6-5) to determine which chemistries require calibration. CX3 chemistries occupy theoretical positions 25-33 and are displayed first because of their calibration frequency. Only chemistries with on-board reagents are displayed. Assign bar code IDs to reagent packs requiring calibration, designated with the letters "nb". Refer to paragraph 6.3.1.2.

NOTE

Most enzymes are electronically calibrated and cannot be requested for calibration by the operator. Example of an exception: ALT-.

CALIBRATION CONSOLE:		3: STANDBY 4: STANDBY	Jun 27 95 10:35
<select> chemist</select>	ries for calibration		(more)
LOC CHEM	RGT LOT # TIME LEF	T STATUS	
25 BUN3 26 GLU3 27 CRE3 28 TP3 nb 29 NA 30 K 31 CL 32 CO2 33 CALC 1 ALB 2 ALT 3 PHOS 4 CHOL 5 ALB	N/A N/A N/A N/A N/A N/A N/A N/A N/A 311223 - 01:03: 502161 408025 - 01:03: 401169 - 01:03:	N/A 25 * Calibration timed out 22 * Calibration timed out	n
5 ALB ASSIGN SEC/CUP F1 F2	404234 00:02: CAL CHEM OVERRIDE BYPASS F3 F4	01 Calibrated EXTEND CAL CAL VER/ CAL TIME OPTIONS LIN F5 F6 F7	LOT STATUS F8
11 12	13 14		14905s.eps

Table 6-5. Calibration Status in Bar Code Mode (Refer to Appendix D for a comprehensive status matrix.)

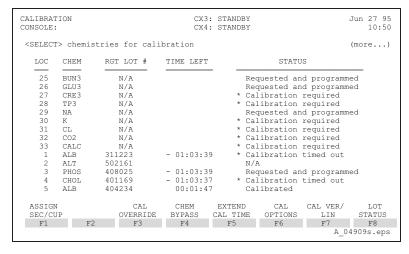
STATUS	DESCRIPTION
Requested and Programmed	Indicates that calibration is pending and bar codes have been assigned for calibrators.
Calibrated	Indicates that the chemistry has been calibrated and has not exceeded its calibration time period.
Calibration Required	Appears when a new cartridge is loaded, a user-defined cartridge is loaded, the system temperature has been reset, or a non-overrideable calibration failure has occurred. Also appears when an ISE instrument reboot has taken place.
Cal Overridden	Operator-initiated; results are based on the failed calibration.
Chem Bypassed	Operator-initiated; allows analysis to proceed on all other chemistries without having to deprogram the bypassed chemistry. A bypassed chemistry must be recalibrated to run. (Refer to paragraph 6.3.3 to Undo Bypass of Noncalibrated Chemistries.)
Failed Calibration	Indicates that a chemistry has exceeded calibration acceptance limits.
Cal Timed Out	Time remaining has exceeded the recommended calibration period.
Cal Time Extended	Operator-initiated; indicates that the recommended calibration period has been extended. The chemistry must have a valid current calibration to be extended.
Within Lot Pending	Indicates calibration has been requested for another cartridge with the same lot number. Applies only to chemistries with within-lot capability. (Refer to Paragraph 6.3.9)

 Move the cursor to the chemistries to be calibrated and press SELECT. Use the PAGE UP/PAGE DOWN keys to access additional chemistries. As each chemistry is selected, the status will change to Requested and Programmed.

NOTE

A calibration request may be deselected by pressing SELECT at the specific highlighted location. However, the analyzer must not have started processing the calibration.

- 4. Load the bar coded samples on to sectors and place on the analyzer.
- Return to MASTER Screen, or CAR-OUSEL STATUS Screen, and press START to initiate calibration.



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6.3.1.4 Manual Cup Assignment for Calibrators

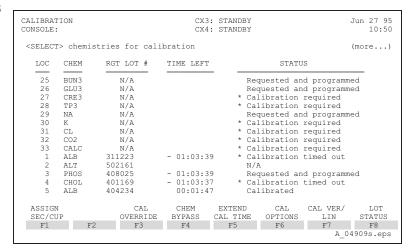
When running the instrument in bar code mode, an operator may assign a calibrator bar code ID to a sector/cup position in place of using a bar code label. A manual cup assignment is used when a bar code label is unavailable or unsuitable, or if the sample must be run in a cup.

WARNING

Prior to loading sectors for use in the bar code mode of operation or programming additional manual cup assignments for a specific sector, ALL manual cup assignments must be cleared. Failure to clear manual cup assignments could result in test results matched with inappropriate patient IDs and demographics.

Assigning the Calibrator Bar Code to a Sector/Cup

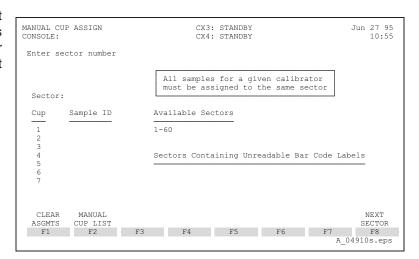
- From the MASTER Screen, press F3 CAL.
- 2. From the CALIBRATION Screen, press F1 ASSIGN SEC/CUP.



 The cursor is active at the sector input field. Available sectors, as well as sectors containing unreadable bar code labels, are displayed on the right side of the screen.

NOTE

Only those sector numbers displayed are allowed as valid entries. Sectors displayed as "Available" contain at least one available cup position. "Sectors Containing Non Readable Bar Codes" contain at least one bar code label that cannot be read. All calibrator levels for a given calibrator must reside on the same sector.



Type an available sector number from either group of sectors displayed, and press ENTER.

WARNING

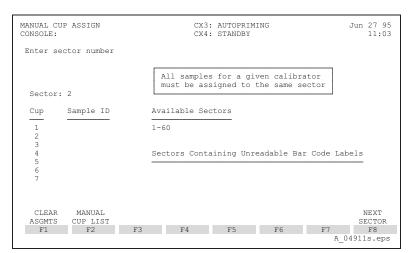
When creating Calibrator Bar Code IDs, use a format that distinctly differs from that used for sample IDs. This will prevent the reporting of erroneous results due to Calibrators being run as Patient Samples, or Patient Samples being run as Calibrators.

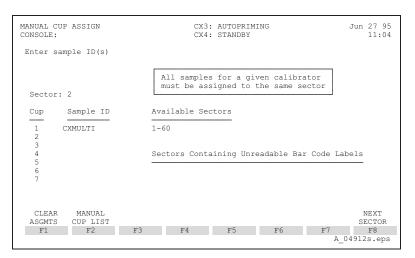
Examples:

Calibrator Bar Code ID: CX MULTI

Sample Bar Code ID: 0000001

- 5. The cursor is active at the first available cup position. If the sector contains bar code IDs which have been successfully read, they are displayed in the appropriate cup positions. Cup positions which are empty or contain unreadable bar codes appear as blank input fields. Enter the bar code ID (Sample ID) to be manually assigned in the first available cup field.
- 6. Continue entering bar code IDs in blank cup fields as necessary. When all entries are complete for the sector displayed, press F8 NEXT SECTOR to continue making manual bar code assignments. To save the assignment and exit the display press PREV SCREEN to return to the main CALI-BRATION Screen or press MASTER SCREEN to return to the MASTER Screen.

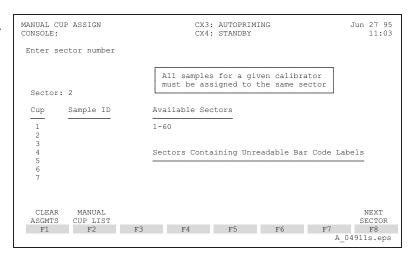




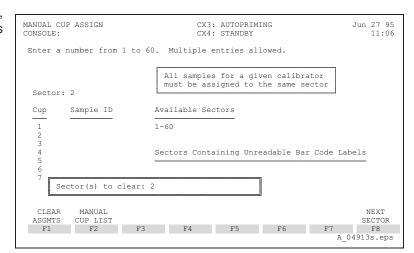
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Clearing Manual Cup Assignments

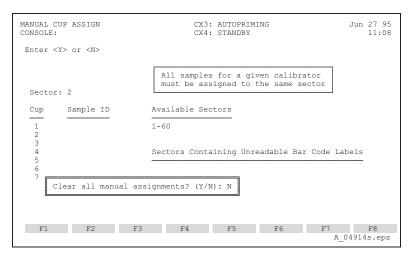
 From the MANUAL CUP ASSIGN Screen, press F1 CLEAR ASSIGN-MENTS.



Type the sector number to be cleared, and press ENTER. Multiple entries are allowed.



- At the confirm prompt, type Y and ENTER to clear all manual cup assignments for the sector entered, or type N and ENTER to cancel the clear request.
- Press PREV SCREEN to return to the main CALIBRATION Screen, or MAS-TER SCREEN to return to the MAS-TER Screen.



Important Notes Regarding Manual Cup Assignments

The following conditions apply to manual cup assignments:

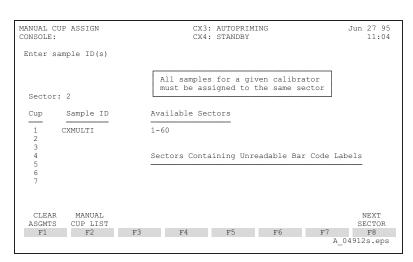
- Operators MUST review all manual cup assignments prior to running, and MUST CLEAR all completed assignments or those which are no longer appropriate. There are several ways that a manual cup assignment can be cleared:
 - (a) The operator can manually clear manual cup assignments.
 - (b) If a sample program is cleared by the operator, all manual cup assignments associated with the sample program are cleared. This applies to unidirectional and bidirectional interfaced systems as well.
 - (c) Manual cup assignments for a sample program with Complete or Incomplete status may be cleared by the host when bidirectional communications are used to transmit sample programming.
 - (d) If the queue exceeds 2000, sample programs which contain manual cup assignments can be overwritten.

- 2. If a sector has a readable bar code and a manual cup assignment for the same sample position, the system will check to make sure that the bar code and the manual assignment match. If there is a discrepancy, the sample will not be processed and the operator notified with a displayed message. (The sector may be immediately off-loaded; or, all other correct bar code sample positions will be processed before off-loading. This option is defined by the operator in Bar Code Setup.)
- 3. All manual cup assignments are lost when there is a switch to bar code mode.
- 4. If the rerun of a manual cup assignment is required, and Host Query is operational, it is possible that the programming for that cup may have already been cleared. This applies to sample programs with Complete or Incomplete status.
- Manual cup assignments are noted on the Master Screen and on the Sample Carousel Status Screen.
- Once manual cup assignments have been made, the Manual Cup Assignment Summary Report should be printed and the assignments verified.

Manual Cup Assignment Load List

A load list for current manual cup assignments can be displayed and/or printed by the operator using a function key on the Manual Cup Assignment screen.

- From the MANUAL CUP ASSIGN Screen, press F2 MANUAL CUP LIST.
- Type the sector number(s) to be included in the load list, and press ENTER. Multiple entries are allowed.
- 3. The load list includes the sector/cup assignment, sample ID (if entered), queue position, sample type, sample status and tests ordered for each manual cup assignment in the sector(s) requested. To print a hard copy of the manual cup assignment load list, press **F1 PRINT**.



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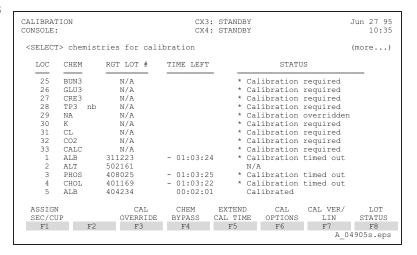
6.3.2 Calibration Override

This option allows the operator to override a failed calibration and obtain results based on the failed calibration factors. Override is available only if an attempt to calibrate the chemistries has been made previously and failed, displaying the status Calibration Failed. A chemistry with any other status, including Calibration Required, cannot be overridden.

Overriding a calibration is not usually justified. However, there may be an emergency situation when a delay caused by calibration is unacceptable to the laboratory. The magnitude of error which is deemed acceptable when overriding a failed calibration is totally under the control of the laboratory and, therefore, the override function should be used with care.

Overriding a Calibration

- 1. From the MASTER Screen, press **F3 CAL**.
- 2. Press F3 CAL OVERRIDE.

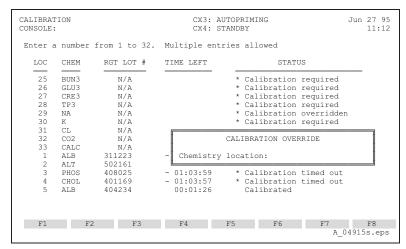


- Type the location number of the chemistries to be overridden and press ENTER.
- 4. The calibration status will display the updated information. The Cal Overridden status can only be removed by successfully recalibrating the chemistry or by selecting Chem Bypass (refer to Chemistry Bypass, Paragraph 6.3.3).

NOTE

A flag indicating that a particular chemistry has been overridden will appear in the Instrument Code section on the results report (refer to Appendix B for a list of the codes).

Press PREV SCREEN or MASTER SCREEN to exit.

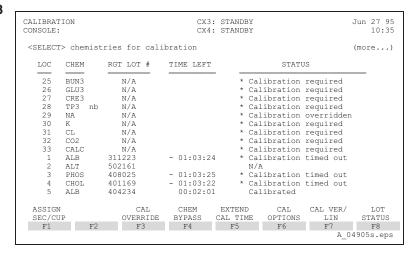


6.3.3 Chemistry Bypass

In the event of a calibration failure on a chemistry which has previously programmed samples, this feature allows the operator to proceed with the analysis of all other programmed tests without having to deprogram the failed chemistry. The system will not aspirate sample or dispense reagents for bypassed chemistries. All bypassed chemistries are logged on the Post Run Summary Report (refer to Paragraph 6.4.7).

Bypassing a Chemistry

- From the MASTER Screen, press F3 CAL.
- 2. Press F4 CHEM BYPASS.

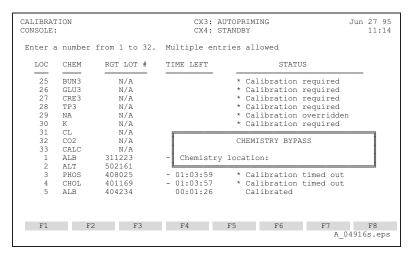


- Type the location number of the chemistry to be bypassed and press ENTER.
- 4. The calibration status will display the updated information.

NOTE

Once a chemistry is bypassed it must be recalibrated to run.

5. Press PREV SCREEN or MASTER SCREEN to exit.



Undo Bypass of Non-calibrated Chemistries

This option provides a mechanism to undo the bypass of chemistries which have methodologies that do not require calibration, such as certain enzymes. This option will not function with chemistries requiring calibration.

- 1. From the MASTER Screen, press F3 CAL, then F4 CHEM BYPASS.
- 2. Type in the location of the bypassed non-calibrated chemistry, then press **ENTER**. The status will change to N/A and be operational.

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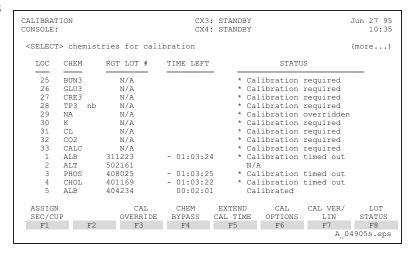
6.3.4 Extend Calibration Time

This feature allows the operator to extend a calibration that has exceeded the recommended calibration time in order to obtain results. The system will display a warning message approximately fifteen minutes prior to the calibration timing out. At this time, the operator can choose to recalibrate the chemistry in question or extend the calibration time. A chemistry can be extended if the current calibration for the chemistry is valid but timed out, or valid and not yet timed out, or the chemistry has been bypassed and its previous calibration was valid. Extend Cal is not allowed if the current calibration was overridden or if calibration has already been requested.

If a chemistry is allowed to time out, subsequent results will be suppressed; however, extending the calibration time will allow results to print.

Extending the Calibration Time

- 1. From the MASTER Screen, press **F3** CAL.
- 2. Press F5 EXTEND CAL TIME.

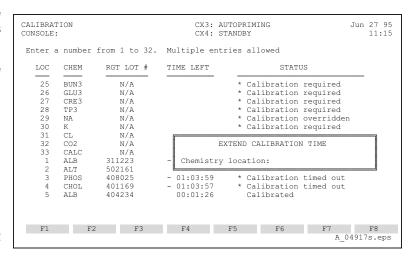


- Type the location number of the chemistries to be extended and press ENTER.
- 4. The calibration status will display the updated information.

NOTE

A flag indicating that calibration time has been extended will appear in the Instrument Code section on the results report (refer to Appendix B for a list of the codes).

Press PREV SCREEN or MASTER SCREEN to exit.



6.3.5 Loading Calibrator Diskettes

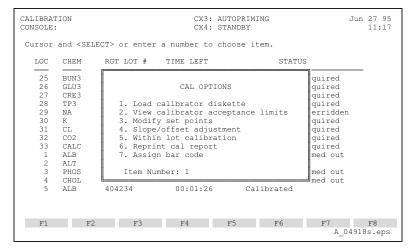
Each calibrator or set of calibrators, has an accompanying diskette which contains the appropriate set points and calibrator-acceptance limits for each particular lot of calibrator. The load calibrator-diskette function allows the operator to load this information into system memory. Only one lot number of each calibrator type is kept in memory. Subsequent lot-number changes will write over the existing calibrator information.

NOTE

The set points and acceptance limits of Drugs, Iron, TIBC, Alcohol, Salicylate, ASO and CX3 (Except TP) calibrators are in permanent memory on the hard drive. Since the values will not vary from lot to lot, no calibrator diskettes are required.

Loading a Calibrator Diskette

- From the MASTER Screen, press F3 CAL.
- 2. Press F6 CAL OPTIONS.
- Cursor and SELECT item 1. Load calibrator diskette, or type 1 and ENTER.
- Place the appropriate diskette into the disk drive. Press ENTER.

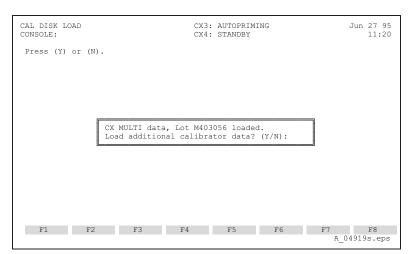


5. Verify that the correct diskette was read from the response on the screen. Press Y if additional calibrator diskettes need to be loaded and repeat Step 4. If no other diskettes are to be loaded, press N.

NOTE

If the incorrect diskette was placed in the disk drive, press **Y** in response to the additional diskette prompt and repeat Step 4 with the correct diskette.

6. Remove the calibrator diskette from the disk drive.



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7. Press **PREV SCREEN** to return to the CALIBRATION STATUS Screen, or press **MASTER SCREEN** to exit.

WARNING

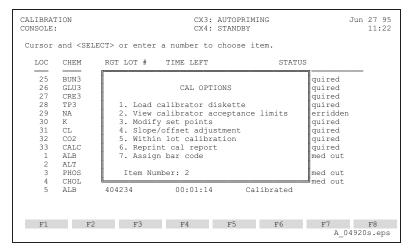
After loading new multipoint calibration (>2 calibration points) diskettes, all chemistries associated with those diskettes MUST be recalibrated before samples are run to avoid incorrect calibration information being applied to the results.

6.3.6 Calibration Acceptance Limits

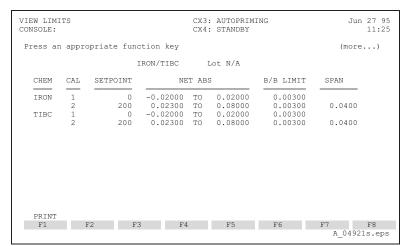
Calibration absorbance or ADC values are compared to preprogrammed back-to-back, span, and range limits to determine acceptable performance. If calibration errors in accuracy, precision, sensitivity, or linearity are detected by the system computer, an error flag is generated. This option provides a reference to the acceptable limits for calibration.

Displaying Acceptance Calibrator Limits

- From the MASTER Screen, press F3 CAL.
- 2. Press F6 CAL OPTIONS.
- Cursor and SELECT item 2. View calibrator acceptance limits, or type 2, ENTER.



- 4. CX4 chemistries are displayed with chemistry name, calibrator level, set-point value, reaction absorbance limits, back-to-back limit, and span. CX3 (except TP) chemistries are displayed with chemistry name, setpoint, ADC range for Cal 1, 2, and 3 back-to-back limit and span (listed with Cal 2 and 3). Digoxin fields displayed are chemistry name, calibrator number, setpoint, reaction absorbance limits, back-to-back limits, and span. Drug (except Digoxin) and protein fields display chemistry name, calibrator number, setpoint and span.
- Use PAGE UP or PAGE DOWN to view additional data. Press F1 PRINT for a printed list (refer to Figure 6-4).
- Press PREV SCREEN to return to the CALIBRATION Screen, or press MASTER SCREEN to exit.



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					17 Jul 9 9:08:40 PAGE 1
		SYNCHRO	N CX7 DE	ELTA	
		CAL	LIMITS		
	Cal Stan	dard 1	Lot N/f	ì	
CHEM	SETPOINT	ADC RA	NGE	B/B LIMIT	SPAN
BUN3	10	-250 TO	-65	20	Obde datab dared areas
GLU3	200	1060 TQ	1650	24	
CRE3	1.0	-140 TO		16	
CO2	Ø	-2000 TO		< 5½	
CL K	4.0	-100 TO		10	
NA NA	20 100	-1185 TO 250 TO		12 15	
CALC	5. 2	-8Ø TO		10	
	Cal Stand	dard 2	Lot N/f	4	
CHEM	SETPOINT	ADC RA	NGE	B/B LIMIT	SFAN
BUN3	80	-1900 TO	-750	20	700
GLU3	50	250 TO	560	24	750
CRE3	8.0	-920 TO		16	390
K	10.0	-700 TO		10	420
CL	180	90 TO	600	12	450
NA CALC	180 14.0	-660 TO -800 TO	-100	15	350
Ŀ™L.Ŀ	14.6	8 <i>2</i> 22 10	-306	10	35Ø
	Cal Stand	dand 3	Lot N/f	a a	
CHEM	SETPOINT	one no	NGE	B/B LIMIT	SPAN

Figure 6-4. Calibration Limits

30

100

20

180.0

-1000 TO

-150 TO

970 TO

-3560 TO -1900

CO2

К

CL

NA

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3500

75

3035

< 5%

10

12

75

450

120

A_05125C.EPS

1100

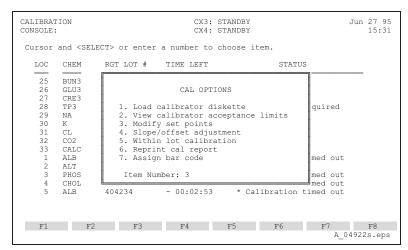
1060

6.3.7 Set-Point Modification

This option allows the operator to change the programmed calibrator set points except for user-defined chemistries. The user-defined chemistry set points may be modified within the user-defined parameters setup; refer to Paragraph 8.2.1. Since most enzyme chemistries are not calibrated, this information does not apply. (Example of exception: ALT-.)

Modifying Calibrator Set Points

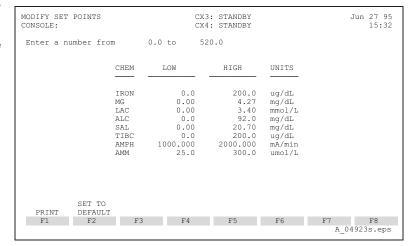
- From the MASTER Screen, press F3 CAL.
- 2. Press F6 CAL OPTIONS.
- 3. Cursor and **SELECT 3**. Modify set points, or type **3**, **ENTER**.



- 4. Use the **PAGE** keys to locate the calibrator of interest.
- 5. Move cursor to the set point to be modified and enter the desired value.

NOTE

A flag indicating that specific set points have been modified will appear in the Instrument Code section on the results report (refer to Appendix B for a list of the codes).



 If a previously modified pair of set points is to be returned to the original default value found on the calibrator diskette or Hard Disk, move cursor to the applicable set point (either low or high) and press F2 SET TO DEFAULT.

NOTE

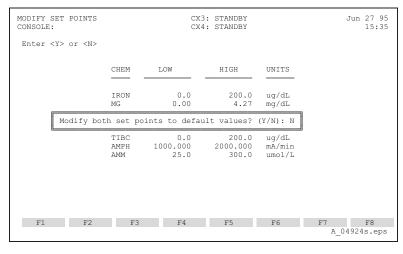
The default values have more significant figures than displayed on the screen. Therefore, use **F2 SET TO DEFAULT**, rather than typing the default values.

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- 7. Press **Y** and **ENTER** to confirm the return to default values or **N** and **ENTER** to cancel request.
- 8. Press **F1 PRINT** to obtain a hard copy of the set points (refer to Figure 6-5).
- Press PREV SCREEN to return to the CALIBRATION STATUS Screen, or press MASTER SCREEN to exit.

NOTE

Recalibration is required after any set-point modification. Calibration status for the chemistry affected will change to "Calibration Required".



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SYNCHRON CX7 DELTA

CX4 Calibration Set Point Report

CHEM	LOW	HIGH	UNITS
ALB	Ø. Ø	4.8	g/dL
ALC	Ø	92	mg/dL
ASO	Ø. Ø	200.0	IU/mL
BUN	0	52	mg/dL
CA	Ø. Ø	11.6	mg/dL
CHOL	Ø	218	mg/dL
CREA	0.0	4.7	mg/dL
CR-T	4.7	0.0	mg/dL
GLU	Ø	155	mg/dL
IRON	Ø	200	ug/dL
LAC	0.0	3.4	mmo1/L
MG	0.0	4.3	mg/dL
PHOS	0.0	7.5	mg/dL
SAL	ଥ. ଥ	20.7	mg/dL
TG	Ø	190	mg/dL
TG-B	Ø	120	mg/dL
TIBC	Ø	200	ug/dL
TP	0.0	8.0	g/dL
TRIG	(2)	Ø	mg/dL
URIC	0.0	8.2	mg/dL
AMM	25	300	umol/L

CX3 Calibration Set Point Report

CHEM	CAL1	CALS	CAL3	UNITS
BUN3 GLU3 CRE3 CO2 K CL NA CALC	10 200 1.0 0 4.0 20 100 5.0	80 50 8.0 10.0 180 180	30 180.0 100 20	mg/dL mg/dL mg/dL mmol/L mmol/L mmol/L mmol/L

CX3 Calibration Set Point Report

CHEM	TP	CAL1	TP	CAL2	UNITS
					·
TP3		3.5		7.5	g/dL

Figure 6-5. Calibration Set-Point Report

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6.3.8 Slope and Offset Adjustment

This option allows the operator to adjust the slope or offset (y-intercept) of the regression equation used for results calculations. This option may be used to modify general chemistries (CX4), enzymes, therapeutic drugs, immunoproteins, and user-defined chemistries. Modifications are made on a per chemistry basis and not per reagent pack.

When this modification is desired, the slope and offset values to be used must be experimentally derived from statistically significant patient correlation studies. It is recommended that patient samples be run over a period of several days by both methods with controls used to monitor accuracy. One should also attempt to achieve a good range of data by analyzing below normal, normal, and above normal samples. Patient sample data (only) should be used for linear regression analysis with SYNCHRON values as y values and the other method values as x values. A minimum of 40 patient samples is recommended. From this analysis, the regression equation in the following form is obtained:

It is necessary to rearrange the above equation to obtain the desired slope and offset values for entry into the SLOPE/OFFSET adjustment screen (since the SYNCHRON values need to be multiplied by the slope value followed by addition of the offset value):

$$x = (y - b) / m$$

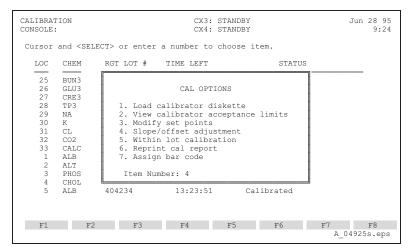
 $x = (y * 1 / m) + (-b / m)$

Slope = 1 / m Offset = -b / m
Value to be entered Value to be entered

Reported sample result = SYNCHRON calculated sample result * (slope) + offset.

Adjusting the Slope or Offset

- 1. From the MASTER Screen, press **F3 CAL**.
- 2. Press F6 CAL OPTIONS.
- Cursor and SELECT 4. Slope/off-set adjustment, or type 4, ENTER.



4. Move cursor to the desired chemistry and enter the new slope or offset value.

For example: ALPd slope = 0.970 offset = 2

NOTE

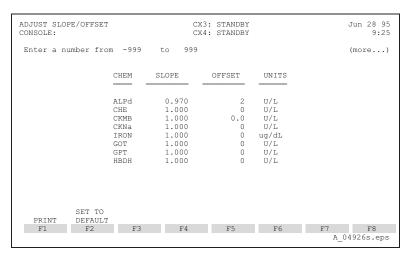
A flag indicating that an adjustment has been made will appear in the Instrument Code section on the results report (refer to Appendix B for a list of the codes).

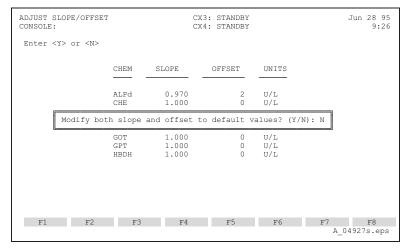
 If a previously modified slope and offset are to be returned to the original default values, move cursor to the applicable chemistry and press F2 SET TO DEFAULT.

NOTE

Use **F2 SET TO DEFAULT** rather than typing the default values.

- Press Y and ENTER to confirm the return to default values or N and ENTER to cancel request.
- 7. Press **F1 PRINT** to obtain a hard copy (refer to Figure 6-6).
- Press PREV SCREEN to return to the CALIBRATION screen, or press MAS-TER SCREEN to exit.





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SYNCHRON CX7 DELTA

Calibration Slope - Offset Report

Chem	Slope	Offset	Units	
	and the contract of the contra	The second secon	THE STATE STATE FOR SHALL MAY SEEN SEE.	
ALS	1.202	7.7	g/dL	
ALC	1.200	Q ₁	#g/dL	
ASO	1.000	0.0	IŪ/mL	
BUN	1.000	₽ t	my/dL	
CA	1.000	ଅ.ଫ	mg≠dL.	
CHOL	1.000	Ø	mg/dL	
CREA	1.000	ଅ.ଓ	mq/dL	
CR-T	1.000	Ø. 2	mq/dL	
OBIL	1.00	ହା. ଅ	mg/dL	
GLU	1.220	Ø	mm/dL	
HDLC	1.000	₹ <u></u> 2)	mq/dL	
IRON	1.202	Ø	ug/dL	
LAC	1.202	Ø. Ø	m m o l/L	
MG	1. 222	Q). (2)	mg/dL	
M-TP	1.000	12)	ag/dL	
PHOS	1.000	Ø. Ø	mg/dL	
F04	1.000	0.2	mg/dL	
SAL	1.002	0.0	mg/dL	
T4	1.000	ZI. (Z)	ug/dL	
TBIL	1.000	Ø. Ø	mg/dL	
TG	1.000	(2)	mq/dL	
TG-B	1.000	21	mg/dL	
TIBC	1.000	12)	ug/dL	
TP	1.000	0.0	q/dL	
TRIG	1.000	(2)	mg/dL	
TU	1.000	0.0	100 554 × 3000 tons	
URIC	1.000	Ø. Ø	mg/dL	
DIG	1.000	21. (2)	ng/mL	
GENT	1.000	Ø. Ø	ug/mL	
PHNB	1.000	0.0	ug/mL	
FHNY	1.000	Ø. Ø	ug/mL	
THEO	1.000	Ø. Ø	ug/mL	
TOBR	1.000	2.0	ud/wr	
ALP	1.000	Ø	IU/L	
ALPd	1.000	Ø	U/L	
ALT	1.000	21	IU/L	
ALT-	1.000	Ø	IU/L	
AMY	1.000	Ø	U/L	
AST	1. 2032	Q Q		
AST-	1.000		IU/L	
CHE		Ø O	IU/L	
Cort Dia	1.000	[2]	UZL	A_05127C.E

Figure 6-6. Calibration Slope Offset Report

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6.3.9 Within-Lot Calibration

The within-lot calibration feature allows the operator to load multiple reagent cartridges of the same lot number without having to calibrate each cartridge. The calibration factor established from a fresh cartridge will be stored and applied to subsequently loaded cartridges of the same lot.

The length of time a within-lot calibration factor remains valid (its within-lot calibration frequency) depends on the chemistry (refer to Table 6-6). During this time any newly loaded cartridge with the same lot number will receive the calibration status Calibrated. At the end of this frequency period, a new within-lot calibration factor must be established from a fresh cartridge.

NOTE

The calibration frequency of a particular cartridge has priority over the within-lot calibration frequency. If a cartridge selected for within-lot calibration is still loaded at the end of its individual calibration frequency period, that cartridge must be recalibrated (this will not affect the within-lot calibration factor).

Only one (1) within-lot calibration factor per lot can be stored in memory. Any time a new cartridge is calibrated for within-lot use, the previous within-lot calibration factor will be overwritten. The system allows storage of up to 150 lots at a time.

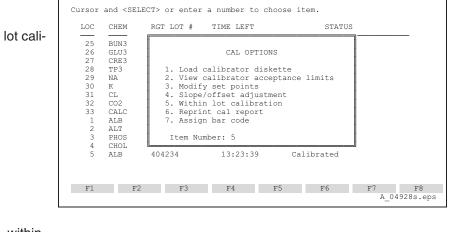
Table 6-6. Individual and Within-lot Calibration Frequencies

Chemistry	Cal Frequency	Within-Lot Cal Frequency
NA, K, CL, CO ₂ , CA3, CALC (ISE) BUN3, URE3, GLU3, CRE3	24 hours	N/A
TP3	7 days	N/A
DIG	3 days	N/A
BUN,UREA	24 hours	30 days
T4, TU	24 hours	N/A
CREA, CR-T	7 days	30 days
ALC	4 days	N/A
AMM, LIPA, AST-, ALT-	5 days	N/A
TP, MG	7 days	90 days
AMPH, BARB, BENZ, COCM, LAC, METD, OP, PCP, SAL, THC, THC5	7 days	N/A
CA	14 days	30 days
CAR, GEN, PHE, PHY, THE, TOB, VPA	14 days	42 days
GLU, URIC, CHOL, ALB, TBIL, DBIL, HDLc, M-TP, TG, TG-B	14 days	90 days
PHOS, PO4	14 days	60 days
THEO, GENT, TOBR, PHNY, PHNB, IgG, IgM, IgA, TRF, FE, IBCT, IRON, TRIG, TIBC, ASO, METQ, PROX, THC2	14 days	N/A
CK-	21 days	N/A
ASO-, CRP, RF	30 days	42 days

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6.3.9.1 Enabling Within-Lot Calibration

- 1. From the MASTER Screen, press **F3 CAL**.
- 2. Press F6 CAL OPTIONS.
- Cursor and SELECT 5. Within lot calibration, or type 5, ENTER.



CX3: STANDBY

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CALIBRATION

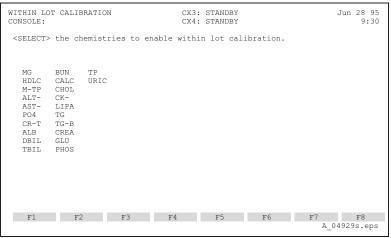
4. The screen displays only the within-lot-capable chemistries which have been configured. To enable within-lot calibration, move the cursor to the desired chemistry and press the SELECT key. The selected chemistry or chemistries will be displayed in reverse video. Pressing the SELECT key again will turn off the within-lot calibration mode for that chemistry and cause the reverse video to return to normal.

NOTE

If the within-lot calibration mode is turned off, any existing cartridges that are using the within-lot calibration factor will retain that factor until the cartridge is used up or the operator requests another calibration. When the operator de-selects a chemistry, the following message appears:

If chemistries are deselected, a new calibration factor will need to be generated for all subsequent reagent packs loaded. Do you want to save changes to within lot chemistries? Y/N

5. To return to the CALIBRATION Screen, press PREV SCREEN. The designations wf, w, and ws follow the reagent lot numbers of those chemistries selected for within-lot calibration. These designations are defined in Table 6-7.



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- wf Reagent has been enabled for within-lot calibration and the cartridge has been "freshly" loaded. Any wf-designated cartridge can be used to establish a within-lot calibration factor. A cartridge receives this designation only if it meets the following two conditions:
 - 1. It was loaded onto the system for the first time after within-lot calibration was turned on; and
 - 2. No more than eight (8) hours have lapsed since it was first loaded onto the system.
- w Reagent has been enabled for within-lot calibration. A cartridge receives this designation if:
 - 1. It was loaded for the first time after within-lot calibration was turned on; and
 - 2. More than eight (8) hours have lapsed since it was first loaded onto the system.
- ws Reagent has been enabled for within-lot calibration but is a stand alone (the calibration factor currently used applies only to this cartridge). A reagent receives this designation under the following conditions:
 - 1. The cartridge was loaded before the within-lot calibration function was turned on; or
 - 2. More than eight (8) hours have lapsed since the cartridge was first loaded (it has a w designation), and the cartridge is recalibrated; or
 - 3. More than eight (8) hours have lapsed since the cartridge was first loaded (it has a w designation) and a fresh reagent of the same lot is calibrated for within-lot use; or
 - 4. The calibration status for the reagent becomes Cal timed out; or
 - 5. Within-lot calibration expires.

CAUTION

Cartridges used to establish a within-lot calibration factor should not be left uncapped for any length of time before loading on the system.

NOTE

Within lot calibration factors may be lost and the calibration status will go to "Calibration Required" after a reboot (using reboot option 1) if:

- 1. The within lot calibration factor was established for a chemistry whose setpoints have since been modified; or,
- The cartridge used to establish the within lot calibration factor has been recalibrated, OR if the reagent record for the cartridge used to establish the calibration factor has been deleted from the database.

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6.3.9.2 Calibrating a Reagent Lot

1. If a newly loaded cartridge has the same lot number as one previously within-lot calibrated, it will automatically receive the correct calibration status; calibration is not necessary.

NOTE

If the calibrator set point is modified, the within-lot calibration factor is lost and the calibration status becomes Calibration Required. This does not apply to the slope and offset adjustment.

- 2. If the lot number of the reagent is new to the system, the calibration status is Calibration Required for all cartridges of that lot on the system. Calibrate the reagents selected for within-lot calibration using the same method for calibrating other reagents. (Refer to Requesting a Calibration under Paragraph 6.3.1, Chemistry and Drug Calibration, in this manual.) Please note the following:
 - (a) Only cartridges designated with a **wf** may be used to establish a within-lot calibration factor.

NOTE

If a cartridge has a **w** designation and the operator requests a calibration on it (e.g., the calibration frequency has expired), the cartridge will receive a **ws** designation and a new calibration factor. The within-lot calibration factor is no longer associated with this cartridge and the new calibration factor does not affect any other cartridge of the same lot number.

- (b) When the operator requests a calibration, only the status of the requested cartridge changes to Requested. If additional cartridges of the same lot are designated **wf**, they receive a calibration status of Within Lot Pending. When the calibration is completed, all **wf**-designated cartridges of the same lot display the same status (Calibrated, Calibration Failed, or Overridden).
- (c) If the operator does not like the calibration (i.e., controls are out of spec), the within-lot calibration factor may be re-established in one of two ways:
 - (1) If the cartridge still has a **wf** designation, the operator may request another calibration. The new calibration factor will automatically override the previous one.
 - (2) The operator may request a calibration of another **wf**-designated cartridge of the same lot. This also will automatically override the old calibration factor.

6.3.9.3 Within-Lot Status

When the system is in operation, an error window will open 24 hours before the within-lot calibration time actually expires, and again two (2) hours before timing out. The following message is displayed:

"Within lot calibration for one or more chemistries will expire in 24 (or 2) hours. Recalibrate with a fresh cartridge to establish a new factor."

Press PREV SCREEN to close the window.

If the within-lot calibration time runs out, the calibration status of a newly loaded cartridge will be Calibration Required. Any previously opened cartridge with the old within-lot calibration factor will remain calibrated until its individual calibration expires. Table 6-8 illustrates a sequence of events that might occur while using within-lot calibration with glucose. To determine for which chemistry the within-lot calibration time has expired, refer to the WITHIN LOT CALIBRATION STATUS Screen.

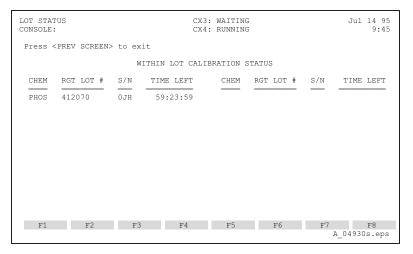
- To display the WITHIN LOT CALI-BRATION STATUS Screen, press F8 LOT STATUS from the CALIBRA-TION Screen.
- 2. The WITHIN LOT CALIBRATION STATUS Screen lists the chemistry with its lot number and the time remaining on the within-lot calibration factor (in days:hours:minutes).
- 3. To return to the CALIBRATION Screen, press **PREV SCREEN**.

NOTE

Serial numbers of cartridges appear in the column labeled S/N. The system can store up to 150 reagent lot records. Each record represents a single within-lot calibration for a particular chemistry and lot number. The record is reused if a subsequent within-lot calibration is performed for the same chemistry and lot. A status of N/A in this column means that the cartridge serial number has been rolled over and that the cartridge has been unloaded.

When a serial number is displayed, either the cartridge is presently loaded, or the cartridge has been unloaded but the serial number has not reached the roll over point.

Expired within-lot calibration records are automatically deleted after 7 days.



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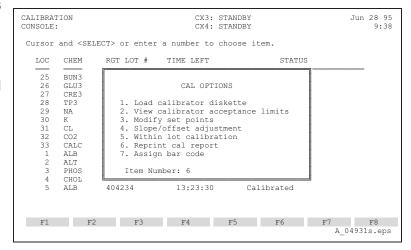
Table 6-8. Example of Within-lot Calibration Use

Day	Event	Glucose Cartridge*	Within-lot Designation	Cal Status
1	G1 loaded and calibrated	G1	N/A	Yes
1	Within-lot calibration enabled for glucose	G1	ws	Calibrated
1	G2, G3 loaded	G1 G2, G3	ws wf	Calibrated Calibration Required
1	Calibration requested for G2	G1 G2 G3	ws wf wf	Calibrated Requested Pending Within-lot Cal
1	G2 calibration complete	G1 G2, G3	ws wf	Calibrated Calibrated
2	G4 loaded	G1 G2, G3 G4	ws w wf	Calibrated Calibrated Calibrated
2	G4 calibrated to re-establish within-lot calibration factor	G1 G2, G3 G4	ws ws wf	Calibrated Calibrated Calibrated
7	G1, G2, G3 depleted and removed; G5, G6 loaded	G4 G5, G6	w wf	Calibrated Calibrated
16	Calibration expires for G4	G4 G5, G6	ws w	Cal Timed Out Calibrated
16	G4 recalibrated; G5 recalibrated (operator option, not required by system)	G4 G5 G6	ws ws w	Calibrated Calibrated Calibrated
21	Calibration expires for G6; G4, G5 depleted and removed	G6	ws	Cal Timed Out
21	G6 recalibrated; G7, G8 loaded	G6 G7, G8	ws wf	Calibrated Calibrated
34	G7 depleted and removed; G9, G10 loaded	G8 G9, G10	w wf	Calibrated Calibrated
47	G8, G9 depleted and removed; G11 loaded	G10 G11	w wf	Calibrated Calibrated
60	G10 depleted and removed; G11 recalibrated (operator option); G12, G13 loaded	G11 G12, G13	ws wf	Calibrated Calibrated
73	G11, G12 depleted and removed; G14, G15 loaded	G13 G14, G15	w wf	Calibrated Calibrated
86	G13 depleted and removed; G15 recalibrated (operator option); G16, G17 loaded	G14 G15 G16, G17	w ws wf	Calibrated Calibrated Calibrated
92	Within-lot calibration expires; G14 depleted and removed; G18 loaded	G15 G16, G1 G18	ws ws wf	Calibrated Calibrated Calibration Required
92	G18 calibrated to establish new within-lot calibration factor	G15 G16, G17 G18	ws ws wf	Calibrated Calibrated Calibrated

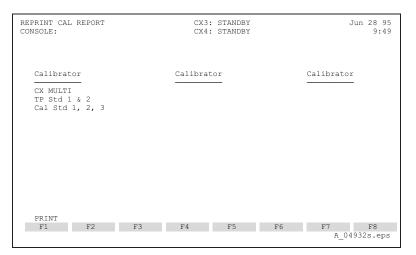
6.3.10 Reprint Calibration Report

Operators may print the last valid calibration for a given calibrator. A copy of the calibration data for the selected chemistries will be printed.

- 1. From the MASTER Screen, press **F3 CAL**.
- From the CALIBRATION Screen, press F6 CAL OPTIONS.
- 3. Cursor and **SELECT 6**. Reprint Cal Report, or type **6**, **ENTER**.



- 4. The screen displays all currently loaded calibrators by name. Cursor and **SELECT** the calibrator to print.
- When all selections are complete, press F1 PRINT to initiate the printed report.
- Press PREV SCREEN to return to the CALIBRATION STATUS Screen, or MASTER SCREEN to return to the MASTER Screen.



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6.3.11 Calibration Verification and Linearity

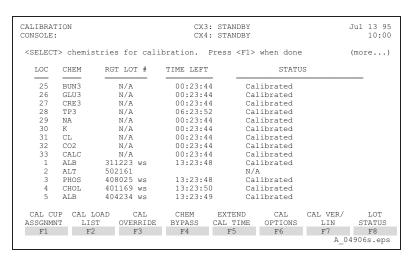
This option allows the operator to define, program and run calibration verification and linearity sets. Upon completion, the system will analyze the data against the defined specifications and generate hard copy printouts of 1) data tables for calibration verification and/or 2) data tables and linear regression plots for linearity. In addition, there is a manual entry feature to allow the operator to edit calibration verification and/or linearity results from the SYNCHRON System. The operator may input off-line data for analysis and printout generation.

6.3.11.1 Set Definition

Define/Review

When defining sets for calibration verification and linearity, note that the sets will be run as defined. For example, if a set is defined to run both calibration verification and linearity for a given group of chemistries, each time the set is run both calibration verification and linearity will be run. If the preferred procedure is to run these separately, then define two different sets for the same set material. One set is for calibration verification and the other set is for linearity (e.g. Enzyme-Verif and Enzyme-Linearity). Up to 7 levels per set may be defined.

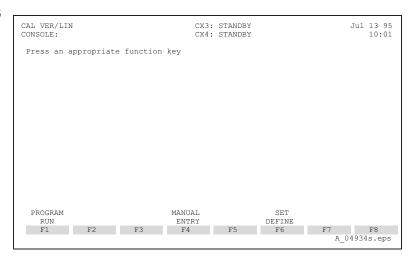
 At the MASTER Screen, press F3 CAL. At the CALIBRATION Screen, press F7 CAL VER/LIN.



2. At the CAL VER/LIN Screen, press **F6 SET DEFINE**.

NOTE

F1 PROGRAM RUN will not be available until at least one set is runnable (defined and reagents loaded on the system) and all applicable reagents are calibrated.

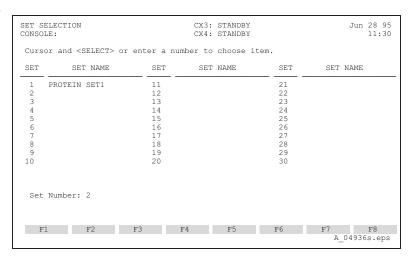


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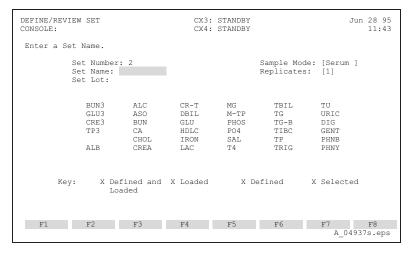
 The SET DEFINITION Screen will display a listing of all defined sets. Press F1 DEFINE/REVIEW.

SET DER	FINITION E:			: STANDBY : STANDBY		Jun 28 95 11:28
Press	the appropri	ate function	key			
SET	SET NAME	SET	SE	T NAME	SET	SET NAME
1 1 2 3 4 5 6 7 8 9 10	PROTEIN SET1	11 12 13 14 15 16 17 18 19 20			21 22 23 24 25 26 27 28 29 30	
DEFIN REVII F1		PRINT SET F3	F4	F5	F6	LAST SET RESULTS F7 F8
LI	12	r J	r d	FJ	r o	A_04935s.eps

4. Type the Set Number to be defined or reviewed and press **ENTER**.



5. The DEFINE/REVIEW SET Screen with currently configured chemistries is displayed with the selected set number. The cursor is active on the first character of the Set Name field. Type in a unique set name of 1 to 20 alphanumeric characters and press ENTER. As soon as the set name is entered, F1 SELECT CHEM and F3 BARCODE ASGMNTS (bar code mode only) become available.

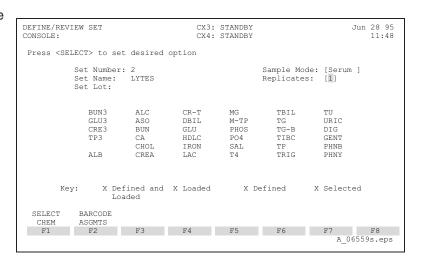


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The cursor is active at the Sample Mode field. Use the SELECT key to toggle between Serum, Plasma, Urine and CSF and press ENTER.

```
DEFINE/REVIEW SET
                                      CX3: STANDBY
                                                                        Jun 28 95
CONSOLE.
                                      CX4: STANDBY
 Press <SELECT> to set desired option.
                                                    Sample Mode: [ Serum ]
Replicates: [1]
           Set Number: 2
           Set Name:
Set Lot:
                       LYTES
                        ALC
ASO
                                                        TBIL
                                                                  TU
URIC
                                             M-TP
                                                        TG
TG-B
TIBC
              GLU3
                                   DBIL
              CRE3
                                   GLU
HDLC
                                                                  DIG
GENT
                         BUN
                                              PHOS
                                             PO4
                        CA
CHOL
                                   IRON
                                             SAL
                                                        TP
                                                                  PHNB
                 X Defined and X Loaded
        Key:
                                                X Defined
                                                                X Selected
 SELECT
CHEM
            BARCODE
ASGMTS
 F1 F2 F3 F4 F5 F6 F7 F8
```

7. At the Replicates field use the **SELECT** key to toggle 1 through 5.



At the Set Lot field (optional), type in the lot number of the set material and press ENTER.

DEFINE/REV	IEW SET			STANDBY STANDBY		Jun 28 95 11:39
Enter a se	et lot numb	er				
	Set Number Set Name: Set Lot:	: 2 LYTES M603-1			Sample Mode: Replicates:	
	BUN3 GLU3 CRE3 TP3	ALC ASO BUN CA CHOL CREA	CR-T DBIL GLU HDLC IRON LAC	MG M-TP PHOS PO4 SAL T4	TBIL TG TG-B TIBC TP TRIG	TU URIC DIG GENT PHNB PHNY
Kej		fined and aded	X Loaded	X D	efined X	Selected
SELECT CHEM	BARCODE ASGMTS					
F1	F2	F3	F4	F5	F6	F7 F8 A_06560s.eps

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 Press F1 SELECT CHEM. The cursor is active on the first configured chemistry. Cursor and SELECT chemistries to be included in the set definition. Use the PAGE UP/PAGE DOWN keys to access additional chemistries.

NOTE

Like sample programming, chemistries with gray letters are configured chemistries. Chemistries with bright green letters are configured and loaded on the system. Compare the display color of the chemistry to the legend at the bottom of the DEFINE/REVIEW SET Screen to determine the status. Refer to Table 6-9 to explain these status states.

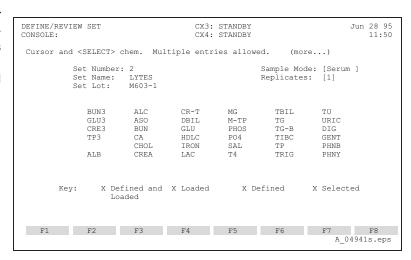
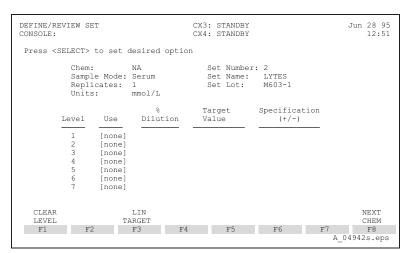


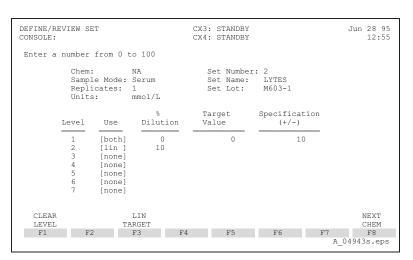
Table 6-9. Chemistry Status for Calibration Verification/Linearity

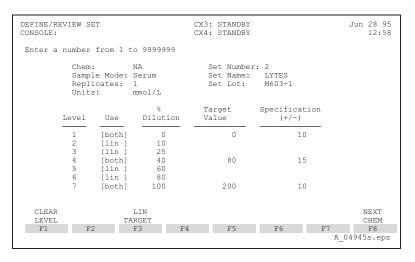
Chemistry Status	Color	Meaning		
Defined and Loaded	Blue letters, dark green background	Chemistry is configured, loaded and defined.		
Loaded	Green letters, gray background	Chemistry configured, loaded, selected, but undefined.		
Defined	Bright blue letters, gray background	Chemistry is configured and defined, but not loaded.		
Selected	Blue letters, gray background	Chemistry is configured and selected, but not loaded or defined.		

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- 10. When all chemistries are selected, press F8 CONTINUE. The definition screen for the first selected chemistry of the set is displayed with 7 definable levels. The cursor is active on the first Use field. Use the SELECT key to toggle between ver (verification), lin (linearity), both and none.
 - (a) If verification or both is selected, the target and specification fields must be filled in
 - (b) If linearity or both is selected, use the F3 function key to toggle between LIN DILUTION (%Dilution) and LIN TARGET (Target Value) to establish which values will be used for linearity analysis. The selected column header will be highlighted and the cursor active in that column. The default is %Dilution.
 - (c) If none is selected, the %Dilution, Target Value and Specification fields are ignored (even if data is present) and inaccessible.
 - (d) Each level must be adequately defined for the Use selected for the cursor to advance to the next level.
 - (e) At least 3 levels must be defined for the set to be runnable.
 - (f) The %Dilution field for each level must be the same for all chemistries within a set. Therefore, the %Dilution entered will be applied to all set chemistries.
- 11. Continue to define all levels applicable for the chemistry. To delete level entries, move the cursor to that level and press F1 CLEAR LEVEL to delete level entries and return the Use field to none.
- 12. When complete, press F8 NEXT CHEM to display the definition screen for the next selected chemistry. Continue the process for all selected chemistries.





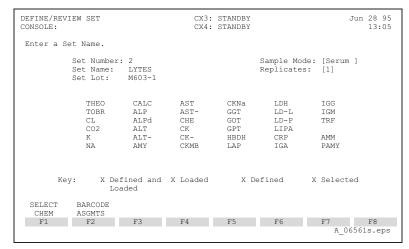


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13. Press **PREV SCREEN** to return to the main DEFINE/REVIEW SET Screen. To define bar codes for the set (bar code mode only) go to step 3 of BAR CODE ASSIGNMENTS, below. To exit press **MASTER SCREEN**.

Bar Code Assignments (Bar Code Mode Only)

- The Set Name must be entered before the bar code assignment softkey, **F2 BARCODE ASGMTS**, will be available.
 - At the SET DEFINITION Screen, press F1 DEFINE/REVIEW.
 - 2. Type the Set Number and press **ENTER**.
 - The DEFINE/REVIEW SET Screen of the selected set is displayed. Press F2 BARCODE ASGMTS.



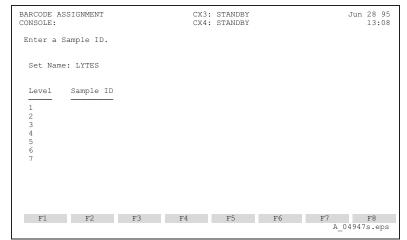
- 4. The cursor is active at the Sample ID field of the first level. Type in the bar code identification and press ENTER. Repeat for each applicable level.
- Press PREV SCREEN to return to the DEFINE/REVIEW SET Screen or MASTER SCREEN to exit.

WARNING

When creating Calibration Verification and Linearity Bar Code IDs, use a format that distinctly differs from that used for sample IDs. This will prevent the reporting of erroneous results due to Calibration Ver/Lin Samples being run as Patient Samples, or Patient Samples being run as Calibration Ver/Lin Samples.

Examples:

Cal Ver/Lin Bar Code ID: LYTES VER01 Sample Bar Code ID: 0000001

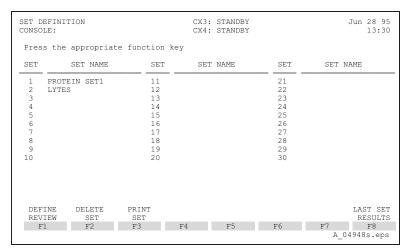


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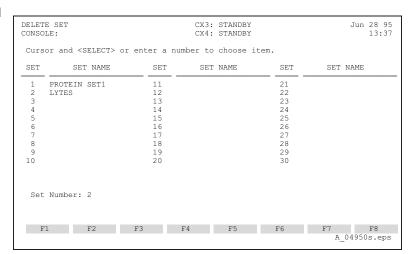
Delete A Set Definition

This option allows the operator to delete a previously defined set along with all specifications and associated results.

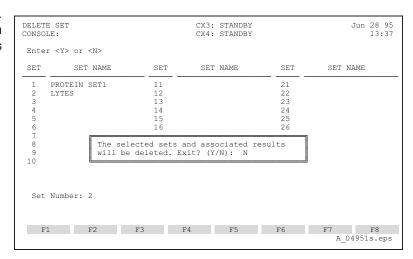
- At the MASTER Screen, press F3 CAL. At the CALIBRATION Screen, press F7 CAL VER/LIN.
- At the CAL VER/LIN Screen, press F6 SET DEFINE.
- 3. At the SET DEFINITION Screen, press **F2 DELETE SET**.



4. Type the set number to be deleted and press **ENTER**.



A confirmation message will appear.
 Type Y and press ENTER to confirm deletion of the set. Type N and press ENTER to cancel deletion of the set.



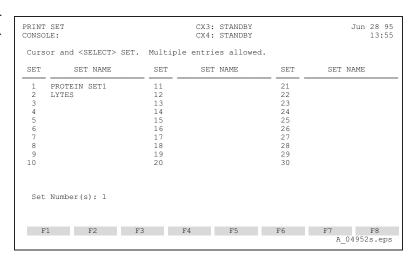
Print Set Definitions

This option allows the operator to print the set definition(s) for the defined sets.

- At the MASTER Screen, press F3 CAL. At the CALIBRATION Screen, press F7 CAL VER/LIN.
- At the CAL VER/LIN Screen, press F6 SET DEFINE.
- 3. At the SET DEFINITION Screen, press **F3 PRINT SET**.

SET DEFINI CONSOLE:	ET DEFINITION ONSOLE:			CX3: STANDBY CX4: STANDBY			Jun 28 95 13:30		
Press the	e appropriat	e function l	сеу						
SET	SET NAME	SET	SET	r name	SET	SET	NAME		
1 PROT 2 LYTE 3 4 5 6 6 7 8 9	EIN SET1 ES	11 12 13 14 15 16 17 18 19 20			21 22 23 24 25 26 27 28 29 30				
DEFINE REVIEW F1	DELETE SET F2	PRINT SET F3	F4	F5	F6	F7	LAST SE RESULT F8		

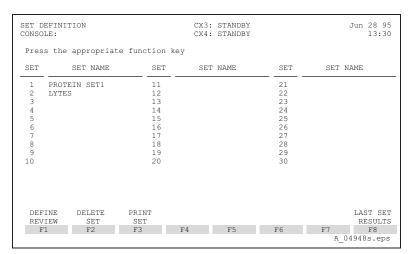
 Type the set number(s) of the definitions to be printed and press ENTER. Multiple entries are allowed.



Print Report of Last Set Results

This option allows the operator to print the reports and plots for the last run of each set. Runs previous to the last run are overwritten in the database and inaccessible.

- At the MASTER Screen, press F3 CAL. At the CALIBRATION Screen, press F7 CAL VER/LIN.
- 2. At the CAL VER/LIN Screen, press **F6 SET DEFINE**.
- 3. At the SET DEFINITION Screen, press **F8 LAST SET RESULTS**.



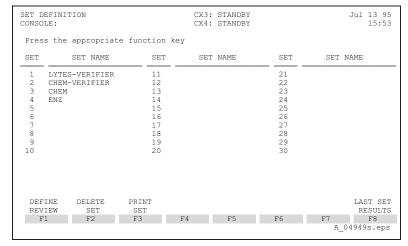
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 Type the set number(s) of the reports to be printed and press ENTER. Multiple entries are allowed.

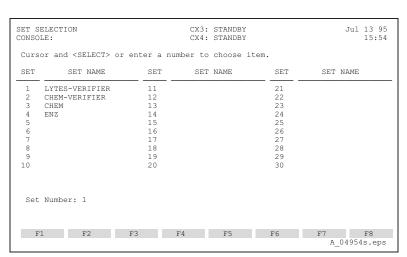
LAST SET RESULTS CONSOLE:			CX3: STANDBY CX4: STANDBY			Jun 28 95 15:34		
Curso	or and <select></select>	SET. Multipl	e entrie	s allowed				
SET	SET NAME	SET	SET	NAME	SET	SET NA	AME	
1	PROTEIN SET1	11			21			
	LYTES	12			22			
3		13			23			
4		14			24			
5		15			25			
6		16			26			
7		17			27			
8 9		18 19			28 29			
10		20			30			
	Number(s): 1							
F1	L F2	F3	F4	F5	F6	F7	F8	
						A 04	1953s.ep	

Review/Edit a Set Definition

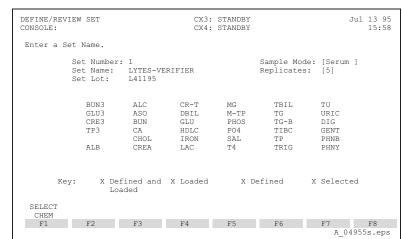
- At the MASTER Screen, press F3 CAL. At the CALIBRATION Screen, press F7 CAL VER/LIN.
- At the CAL VER/LIN Screen, press F6 SET DEFINE.
- The SET DEFINITION Screen will display a listing of all defined sets. Press F1 DEFINE/REVIEW

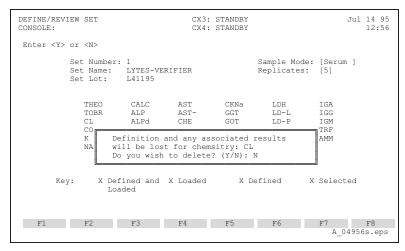


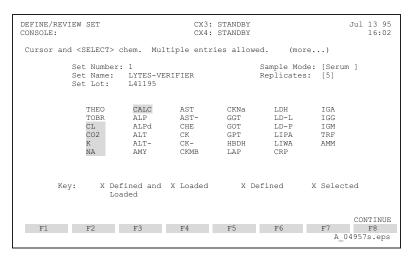
4. Type the Set Number to be reviewed and/or edited and press **ENTER**.



- 5. The operator may view heading information or cursor to and edit, if applicable. Editing of any information will delete the results for the last run. A confirmation window prompts the operator to type N and press ENTER to cancel changes or to type Y and press ENTER to continue with the change and delete the results.
- Press F1 SELECT CHEM to review and/or edit chemistry definitions or to delete chemistries from the set. Press F2 BARCODE ASGMNTS (bar code mode only) to review and/or edit bar code assignments.
- 7. If F1 SELECT CHEM is chosen, the operator may cursor and SELECT to add/delete chemistries from the set definition. If a previously selected chemistry is deselected, all definition specifications and results will be deleted. A warning window is displayed, prompting the operator to confirm the action. Type N and press ENTER to cancel deletion of the chemistry, or type Y and press ENTER to confirm deletion of the chemistry and associated definition and results.
- Chemistries can be added to the set definition by moving to the chemistry position and pressing SELECT. When all additions/deletions are complete, press F8 CONTINUE.

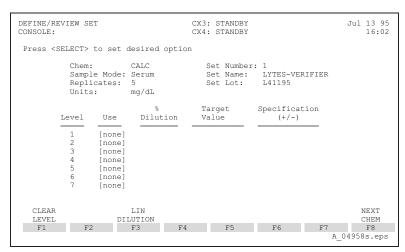






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 The definition screen for the first chemistry of the set is displayed. Review and/or edit the chemistry definition or press F8 NEXT CHEM until the desired chemistry is displayed.



- 10. To edit the definition parameters for the chemistry, move to the appropriate field and overwrite the information. Use F1 CLEAR LEVEL to clear all information for that level and return the Use field to none. If chemistry parameters are changed, previously run results associated with that chemistry will be deleted. A warning window is displayed, prompting the operator to confirm the action. Type N and press ENTER to cancel change to the chemistry parameter, or type ${\bf Y}$ and press ENTER to confirm the change and deletion of the associated results.
- Press PREV SCREEN to return to the main DEFINE/REVIEW SET Screen or MASTER SCREEN to exit.

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6.3.11.2 Programming and Running a Set

This option allows the operator to program and run a previously defined calibration verification and/or linearity set. Each time a set is run the previous run is overwritten in the database and is inaccessible for review. At the successful completion of a calibration verification and/or linearity run, a hard copy report will be automatically printed. Refer to Appendix E for an example of the report. The "x" symbols on the linearity graph represent the mean replicate values of each level. The "o" symbols represent end points of the linearity line through which a line can be manually drawn. The slope represents the actual slope of $\Delta y/\Delta x$. When % dilution is used, a scaled slope is calculated which sets the 100% value (x) equal to the instrument result (y) for this level. All remaining x values are calculated from this value. If results are suppressed, or out of instrument range, asterisks (*) will appear on the report.

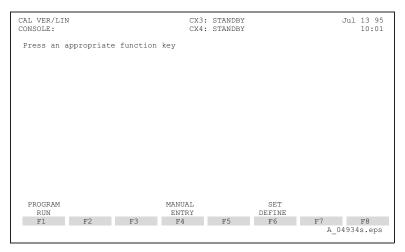
 At the MASTER Screen, press F3 CAL. At the CALIBRATION Screen, press F7 CAL VER/LIN.

CALIBRATION CONSOLE:				STANDBY STANDBY			Jul 13 95 10:00
<select< th=""><th>?> chemi:</th><th>stries for ca</th><th>libration. P</th><th>ress <f1></f1></th><th>when done</th><th>:</th><th>(more)</th></select<>	?> chemi:	stries for ca	libration. P	ress <f1></f1>	when done	:	(more)
LOC	CHEM	RGT LOT #	TIME LEFT		STATU	IS	
25	BUN3	N/A	00:23:44	Cal	ibrated		
26	GLU3	N/A	00:23:44	Ca]	ibrated		
27	CRE3	N/A	00:23:44	Cal	ibrated		
28	TP3	N/A	06:23:52	Cal	ibrated		
29	NA	N/A	00:23:44	Cal	ibrated		
30	K	N/A	00:23:44	Ca]	ibrated		
31	CL	N/A	00:23:44	Cal	ibrated		
32	CO2	N/A	00:23:44	Cal	ibrated		
33	CALC	N/A	00:23:44	Cal	ibrated		
1	ALB	311223 ws	13:23:48	Cal	ibrated		
2	ALT	502161		N/A	4		
3	PHOS	408025 ws	13:23:48		ibrated		
4	CHOL	401169 ws	13:23:50		ibrated		
5	ALB	404234 ws	13:23:49	Cal	ibrated		
CAL CU	JP CAL I	LOAD CAL	CHEM	EXTEND	CAL	CAL VER/	LOT
ASSGNMN	IT LIS	ST OVERRII	E BYPASS	CAL TIME	OPTIONS	LIN	STATUS
F1	F2	2 F3	F4	F5	F6	F7	F8

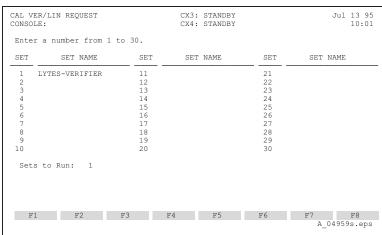
2. At the CAL VER/LIN Screen, press **F1 PROGRAM RUN**.

NOTE

F1 PROGRAM RUN will not be available until at least one set is runnable (defined and reagents loaded on the system) and all applicable reagents are calibrated.

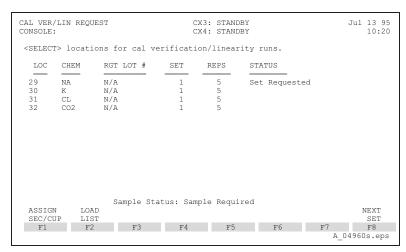


 The CAL/VER LIN PROGRAM Screen will display a listing of all defined and <u>runnable</u> sets. Type the set number(s) to run and press ENTER. Multiple entries are allowed.



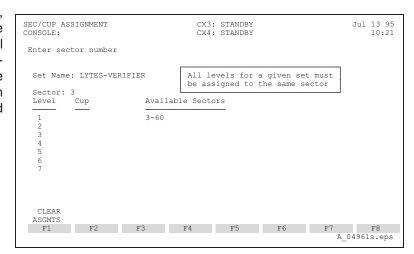
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4. The CAL VER/LIN REQUEST Screen will display all currently loaded chemistries, by reagent position, that are included in the first set definition selected for running from the last screen. The cursor will be active at the first chemistry location. Cursor and SELECT the chemistry reagent positions to be run in the set. Use PAGE UP/PAGE DOWN to access additional chemistry locations and F8 NEXT SET to access additional sets, if requested. For Sector/Cup Mode proceed to step 5. For Bar Code Mode proceed to step 9.



Sector/Cup Mode

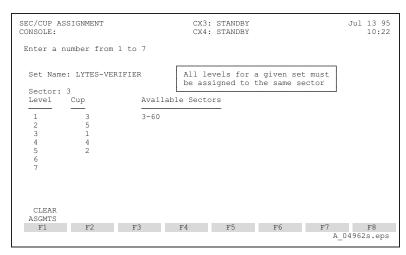
5. When all selections are complete, press F1 ASSIGN SEC/CUP. The SEC/CUP ASSIGNMENT Screen will display the first set selected for programming and running. Using the Available Sectors as a guide, type in the Sector number for the first set and press ENTER.



- 6. Type in the cup position for each applicable level and press **ENTER**.
- 7. If multiple sets were requested, press F8 NEXT SECTOR to assign sector/ cup positions for the remaining sets. Press F1 CLEAR ASGMTS to clear a sector(s) of cup assignments.
- Press PREV SCREEN to return to the CAL VER/LIN REQUEST Screen.
 Press F2 LOAD LIST to print a copy of the load list.

NOTE

It is recommended to use 2.0 mL cups, or larger, to ensure that enough sample is available for multiple replicates.



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Bar Code Mode

9. When all selections are complete, press F2 LOAD LIST to print a copy of the load list. Place the bar coded samples on available sectors. If manual cup assignments are desired, press F1 MANUAL ASGMNTS. The MANUAL ASSIGNMENT Screen will display the first set selected for programming and running. Using the Available Sectors as a guide, type in the Sector number for the first set and press ENTER. Only those sector numbers displayed are allowed as valid entries.

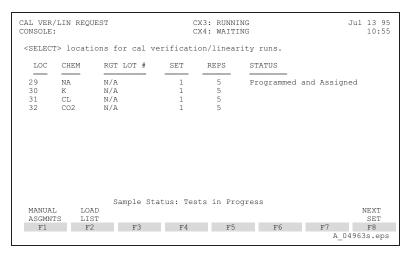
WARNING

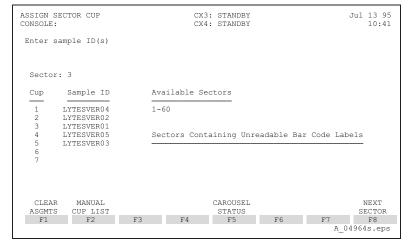
Prior to loading sectors for use in the bar code mode of operation, ALL previous manual cup assignments must be cleared. Failure to clear manual cup assignments could result in test results matched with inappropriate patient IDs. Refer to page 6-42 for 'Important Notes Regarding Manual Cup Assignments."

- Type in the Sample ID and cup position for each applicable level and press ENTER.
- 11. If multiple sets were requested, press F8 NEXT SECTOR to assign Sample ID and sector/cup positions for the remaining sets. Press F1 CLEAR ASGMTS to clear a sector(s) of manual cup assignments.
- Press PREV SCREEN to return to the CAL VER/LIN REQUEST Screen.
 Press F2 LOAD LIST to print a copy of the load list.

NOTE

It is recommended to use 2.0 mL cups, or larger, to ensure that enough sample is available for multiple replicates.



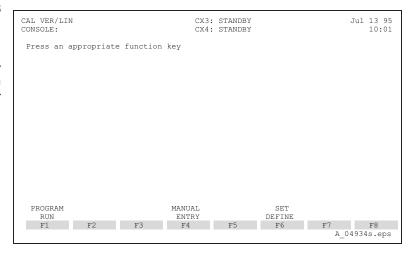


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6.3.11.3 Manual Entry of Calibration Verification/Linearity Data

This option allows the operator to edit the last run of each set or manually enter off-line data for calibration verification and linearity analysis. A hard copy report of the associated tables and plots can then be generated. These reports will contain in their title "Manually Entered".

- At the MASTER Screen, press F3 CAL. At the CALIBRATION Screen, press F7 CAL VER/LIN.
- At the CAL VER/LIN Screen, press F4
 MANUAL ENTRY. To edit the last run
 proceed to step 3. To manually enter
 off-line data proceed to step 7.



Edit The Last Run

3. The MANUAL SET ENTRY Screen is displayed. The cursor is active at the Chemistry field. Type chemistry name (1 to 4 characters) and press ENTER. To edit the last calibration verification or linearity run, type in the exact name of that chemistry as it appears on the system (case sensitive).

```
MANUAL SET ENTRY
                                                              Jul 13 95
                                 CX3: STANDBY
CONSOLE.
                                 CX4: STANDBY
Enter a Chem Name.
Chemistry: NA
               Set Number:
                                      Set Name:
               Sample Mode:
                            [Serum ]
                                       Set Lot:
Hse.
        [none]
                                   [none]
Level:
%Dil:
Target
Specs:
Rep1:
Rep3:
Rep4:
Rep5:
F1 F2 F3 F4 F5 F6 F7
```

4. The cursor is active at the Set Number field. To edit the last run of the set, type in the set number and press ENTER. The system will fill in the Set Name, Units, Sample Mode, Set Lot Number, Use, "Dilution, Target Value and Specification fields from the set definition, and the results from the last run, if available.

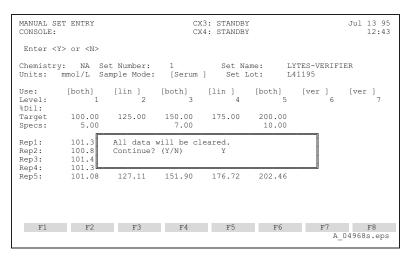
```
MANUAL SET ENTRY
                                   CX3: STANDBY
                                                                  Jul 13 95
CONSOLE:
                                   CX4: STANDBY
                                                                      12:41
Enter a number from 0 to 99
Chemistry:
           NA Set Number:
                                        Set Name:
                Sample Mode:
                              [Serum ]
Hse.
         [none]
                  [none]
                            [none]
                                     [none]
                                               [none]
                                                         [none]
                                                                  [none]
Level:
%Dil:
Specs:
Rep1:
Rep2:
Rep3:
Rep4:
Rep5:
  CALC
            CLEAR
  PRINT
           SCREEN
 F1
          F2
                    F3 F4 F5 F6
```

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 Cursor to and overwrite the data fields to be edited. When editing is complete, press F1 CALC/PRINT to initiate printing of the associated reports.

```
MANUAL SET ENTRY
                                      CX3: STANDBY
CX4: STANDBY
                                                                         Jul 13 95
CONSOLE:
 Enter a number from 0.00 to 999999.00
Chemistry: NA Set Number:
                                                           LYTES-VERIFIER
        mmol/L Sample Mode:
Units:
                                 [Serum ]
                                             Set Lot:
                                                           L41195
                                                                       [ver]
          [both]
                     [lin ]
                               [both]
                                          [lin ]
                                                   [both]
                                                             [ver ]
Level: %Dil:
          100.00
                                150.00
7.00
Target
Specs:
                     125.00
                                          175.00
                                                     200.00
Rep1:
           101.39
                                152.12
                                           176.85
                                                     202.32
           100.85
101.46
101.31
                     126.74
127.49
127.02
                                           176.72
176.60
Rep2:
                                153.10
                                                     201.47
                                151.79
152.55
Rep3:
                                                     201 61
Rep4:
Rep5:
           101.08
                      127.11
                                151.90
                                           176.72
                                                     202.46
                    F3 F4 F5 F6 F7 F8
                                                                      A 04967s.eps
```

 F2 CLEAR SCREEN will clear all data from the screen. A warning note will prompt the operator to confirm clearing the data. Type N and press ENTER to cancel, or type Y and press ENTER to clear all data.



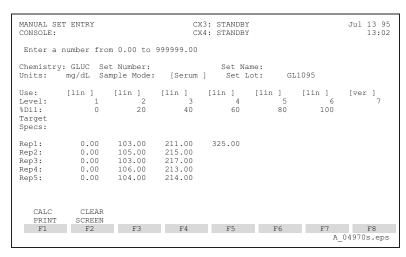
Manual Entry of Off-Line Data

 The MANUAL SET ENTRY Screen is displayed. The cursor is active at the Chemistry field. Type a chemistry name (1 to 4 characters) and press ENTER.

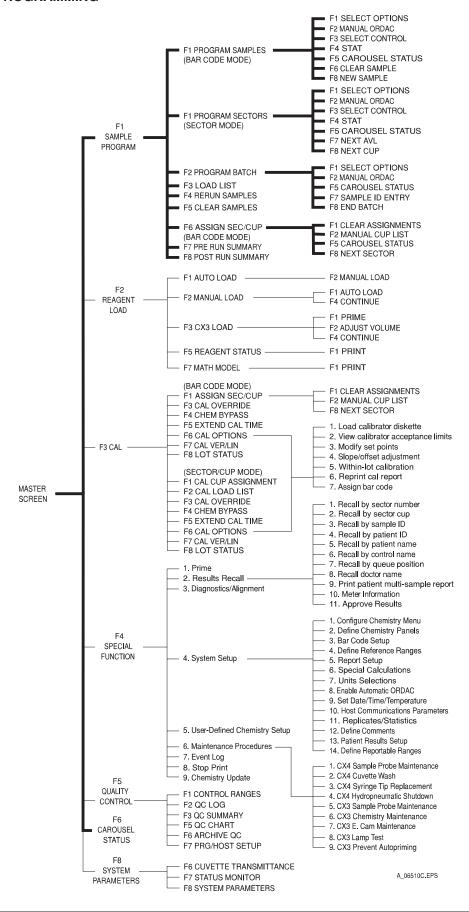
```
MANUAL SET ENTRY
                                                         Jul 13 95
CONSOLE:
                              CX4: STANDBY
Enter a Chem Name.
Chemistry: GLUC Set Number:
Units:
             Sample Mode:
                          [Serum ]
                                   Set Lot:
Use:
        [none] [none]
                      [none]
                               [none] [none]
                                                [none]
                                                        [none]
%Dil:
Target
Specs:
Rep1:
Rep2:
Rep3:
Rep4:
F1 F2 F3 F4 F5 F6 F7
```

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- Cursor to the Set Name, Units, Sample Mode, Set Lot Number, Use, %Dilution, Target Value and Specification fields and type in the information as applicable, keeping in mind the following:
 - (a) Use ENTER or arrow keys to move the cursor between fields and enter data.
 - (b) If verification or both is selected, the target and specification fields must be filled in.
 - (c) If linearity or both is selected and the %Dilution is filled in, the system will use this data for linearity analysis.
 - (d) If linearity or both is selected and only the target and specifications fields are filled in then the system will use those data fields.
 - (e) The system will default to the %Dilution field for linearity data, if available.
 - (f) Data for at least three levels must be supplied.
- When all information is complete, press F1 CALC/PRINT to initiate printing of the associated reports.
- 10. F2 CLEAR SCREEN will clear all data from the screen. A warning note will prompt the operator to confirm clearing the data. Type N and press ENTER to cancel, or type Y and press ENTER to clear all data.



6.4 SAMPLE PROGRAMMING



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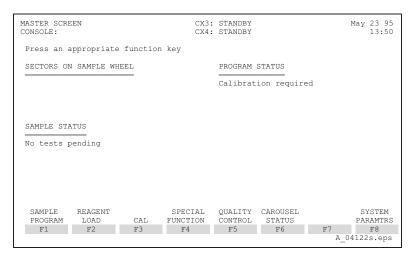
A sample program is used to define the chemistries run on a given sample. Certain areas of Sample Programming are specific to either Sector/Cup mode or Bar Code mode only; these areas are noted in the text. If programming is unaffected by the sampling mode of the instrument, the text will reflect both modes.

6.4.1 Assignment of Samples

6.4.1.1 Sector Selection and Assignment (Sector/Cup Mode Only)

Cups containing patient samples, controls, or calibrators are assigned to sectors which are then loaded onto the system by way of the autoloader for sample processing (refer to Paragraph 5.5). Each sector is uniquely numbered (1 - 60) and can be assigned a maximum of 7 cups. The SECTOR STATUS Screen displays information on the current programming and processing status of all sectors (Table 6-10).

 From the MASTER Screen, press F1 SAMPLE PROGRAM.



 Review the sector status to determine which sectors are available for programming. Press the PAGE UP or PAGE DOWN key to view additional sector numbers.

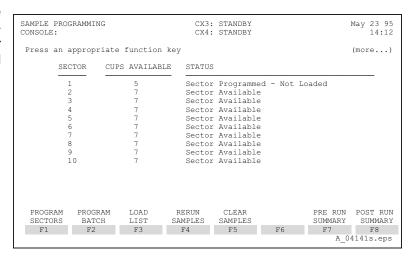


Table 6-10. Sector Status Designations

STATUS	MEANING
Sector Available	May be used for programming.
Sector Completed	Previously programmed samples are done. Sector must be cleared before it can be programmed again.
Partially Completed - Tests Pending	Tests within one or more samples are incomplete. Check Post Run Summary Report for status (Paragraph 6.4.7).
Sector Programmed - Not Loaded	Samples are programmed but not run. Any cup may be changed or reprogrammed at this time.
Testing in Progress	Sector is loaded on system and running. Programming of this sector not allowed.
Reserved for Calibrators	Sector was selected for calibrator-cup assignment from the calibration screen. Sample programming for this sector is not allowed.
Calibration Completed	Previously requested calibration is complete. Sector must be cleared before it can be programmed again.
Calibration in Progress	Sector is loaded on system and selected chemistries are being calibrated. Programming of this sector is not allowed.
Partially Completed - Cal Pending	Tests within one or more calibrators are incomplete. Check Post Run Summary Report for status (Paragraph 6.4.7).

3. Press the function key desired.

F1	Program Sectors	Refer to Paragraph 6.4.1.1.
F2	Program Batch	Refer to Paragraph 6.4.3.1.
F3	Load List	Refer to Paragraph 6.4.5.1.
F4	Rerun Samples	Refer to Paragraph 6.4.4.1.1 and 6.4.4.2.1.
F5	Clear Sectors	Refer to Paragraph 6.4.2.12.
F7	Pre Run Summary	Refer to Paragraph 6.4.6.
F8	Post Run Summary	Refer to Paragraph 6.4.7.

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6.4.1.2 Sample ID Selection and Assignment (Bar Code Mode only)

Primary sample tubes containing patient samples, controls, or calibrators are assigned unique sample IDs, then loaded onto the system by way of the autoloader for sample processing (refer to Paragraph 5.5). Each sample ID is unique within a queue of 2000 sample IDs. The QUEUE STATUS Screen displays the queue number of the sample, the sample ID, sector and cup number (if available), time and date the sample program was created, and the sample status. Six sample status conditions are possible in the bar code mode:

Complete all results are done, no pending tests remain

Incomplete all results that can be performed are finished, but pending tests remain sample Required sample program is resident, system is waiting for the sample to be loaded

Tests in Progress sample is being processed

Removed tests are still in progress, but the sample has been removed from the sample

carousel (Table 6-10).

Rerun sample is programmed for rerun

- 1. From the MASTER Screen, press **F1 SAMPLE PROGRAM**.
- Review the queue status to determine which sample IDs are currently in the queue. Press the PAGE UP or PAGE DOWN key to view additional sample IDs.

SAMPLE PE	ROGRAMMING			X3: STANDBY X4: STANDBY			May 25 95 9:20
Press ar	n appropriate	e function	n key				(more
			PROGRAMM	ED SAMPLES			
Queue	Sample ID	Sector	Cup T	ime-Date Pro	grammed	Sample Sta	tus
62	581	58	1	12:33 - 19	/05	Complete	
58	571	57	1	11:14 - 18	/05	Complete	
57	561	56	1	12:55 - 17	/05	Complete	
55	553	55	3	13:13 - 16	/05	Complete	
54	552	55	2	13:02 - 16	/05	Complete	
53	551	55	1	15:03 - 15	/05	Complete	
44	187	18	7	18:17 - 05	/05	Complete	
43	186	18	6	18:16 - 05	/05	Complete	
42	185	18	5	18:16 - 05	/05	Complete	
41	184	18	4	18:16 - 05	/05	Complete	
40	183	18	3	18:15 - 05	/05	Complete	
39	182	18	2	18:15 - 05	/05	Complete	
PROGRAM	M PROGRAM	LOAD	RERUN	CLEAR	ASSIGN	PRE RUN	POST RUN
SAMPLES	BATCH	LIST	SAMPLE	S SAMPLES	SEC/CUP	SUMMARY	SUMMARY
F1	F2	F3	F4	F5	F6	F7	F8

3. Press the function key desired.

F1	Program Samples	Refer to Paragraph 6.4.2.2.
F2	Program Batch	Refer to Paragraph 6.4.3.2.
F3	Load List	Refer to Paragraph 6.4.5.2.
F4	Rerun Samples	Refer to Paragraph 6.4.4.1.2 and 6.4.4.2.2.
F5	Clear Samples	Refer to Paragraph 6.4.2.13.
F6	Assign Sector/Cup	Refer to Paragraph 6.4.2.3.
F7	Pre Run Summary	Refer to Paragraph 6.4.6.
F8	Post Run Summary	Refer to Paragraph 6.4.7.

6.4.1.3 Sample Carousel Status

The status of up to six sectors currently loaded on the sample carousel can be viewed on the real time CAROUSEL STATUS Screen. The status of each sample is designated by the display color, described by the legend at the top of the screen. In the Bar Code mode, sample IDs are displayed with the corresponding sector/cup position. Samples with unreadable bar code labels are not processed and are not displayed. The **START** key is functional in the CAROUSEL STATUS Screen.

There are four operator selectable host query times available; 2.5 (default), 5.0, 7.5, and 10 minutes. If sample programming was not received from the host within the selected host query time, an asterisk (*) will appear in front of the sample ID. Also, the sample status on MASTER SCREEN will display "(*) Host Query Timed Out."

In the sector mode, Sample IDs will be displayed if they have been entered in Sample Programming. If no sample ID is programmed for the cup, "No ID" is displayed in corresponding field. In either case, the sample status is designated by the display color. Empty cup positions are indicated by a blank field. Manual cup assignments are displayed against a black background.

- 1. From the MASTER Screen, press **F6 CAROUSEL STATUS**.
- Locate the sample desired by sample ID (Bar code mode) or by sector/cup position (sector mode).
- Compare the display color of the sample to the legend at the top of the screen. Refer to Table 6-11 to determine the status of the sample.

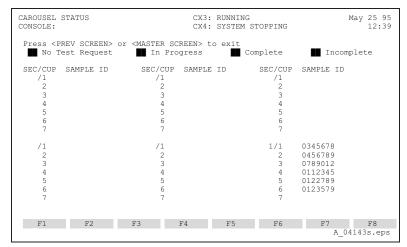


Table 6-11. Sample Carousel Status

Sample Status	Color	Meaning
Complete	White	Sample has been processed and all results are finished.
In Progress	Green	Sample is being processed but results are not complete.
No Test Request	Red	The sample bar code has been read, but either the sample program has not been received or no sample program has been defined for the sample.
Incomplete	Purple	All available test results are in for the sample, but pending tests remain.

4. Press PREV SCREEN or MASTER SCREEN to return to the MASTER Screen.

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6.4.2 Programming Samples

6.4.2.1 Sector/Cup Mode

Sample programming provides the operator with several functions: 1) assignment of a sector and cup number to each sample or control for processing, 2) entering specific information to characterize and identify the sample and its associated results, and 3) test selection and programming. Samples may be characterized through use of the SAMPLE COMMENT, SELECT CONTROL, SAMPLE TYPE and DILUTION FACTOR functions. Identification can be specified by entering a SAMPLE ID number and PATIENT DEMOGRAPHICS. Sample programming allows the operator to optimize test selection by use of the PANELS (as defined by the operator in System Setup, Paragraph 6.5.1.2) and Manual ORDAC functions. In addition, samples can be designated as STAT for priority processing. The **STAT LOAD** button on the autoloader should be activated to expedite the loading of the STAT sample (refer to Paragraph 5.5.3).

NOTE

Pre-treated or pre-diluted tests cannot be programmed in the same sample program as regular tests (i.e., Immunoproteims and TP). These can be added as a rerun (refer to paragraph 6.4.4). When an error occurs in test selection that could potentially involve different sample types, the operator should clear the sample program (refer to paragraph 6.4.2.14) instead of deselecting and reselecting tests.

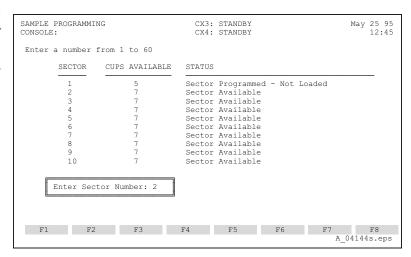
NOTE

In sector/cup mode, the sector/cup position must be assigned and at least one test selected to save the sample program.

- From the SAMPLE PROGRAMMING Screen, press F1 PROGRAM SEC-TORS.
- 2. Type the sector number to be programmed and press **ENTER**.

NOTE

The sector number entered is a starting point. When all seven cups have been programmed, subsequent sectors are automatically incremented in consecutive order unless changed by the operator.

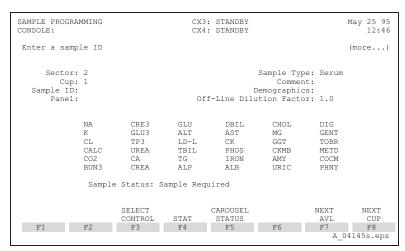


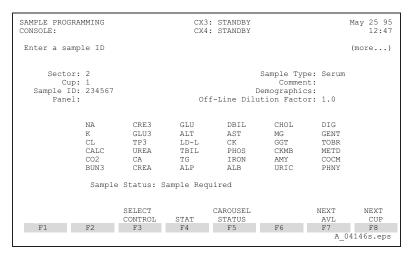
- 3. Upon entering the Sample Program screen, the cursor is active at the Sample ID field. The cup displayed is the first empty cup on the sector. If an alternative cup is desired, move cursor to the Cup field and enter the appropriate cup number. If the cup number is changed, any edits on the current cup will be saved and the screen for the newly designated cup will be displayed. Sample status is displayed as an indicator of sample disposition in regard to testing. Possible status' are displayed in Table 6-12.
- Type the Sample ID (up to 11 alphanumeric characters), and press ENTER. Sample ID is not a required field entry for sector/cup mode.

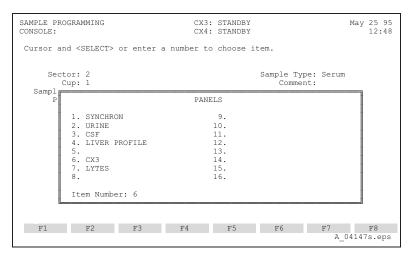
NOTE

Invalid Sample ID characters include *, ?, \$, space, comma and semi-colon. Alpha characters must be entered in upper case.

5. The cursor is active at the Panel input field. If programming using panels, press F1 SELECT OPTIONS to view and select from the list of previously defined panels, or enter the number directly (if known) at the Panel field (refer to Paragraph 6.5.1.2 for further details on defining panels). If programming individual tests, press ENTER or the down arrow to skip this field.





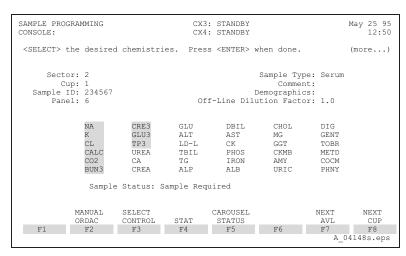


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 Individual tests can be programmed from the chemistry selection area of the screen by cursoring to the desired test, or by using the alpha keys to locate and select chemistries more quickly.

(a) Using the Cursor

Use the cursor control arrows to access the desired test. Press **SELECT** to program unassigned chemistries or to deprogram assigned chemistries. Continue to cursor and **SELECT** additional chemistries as desired. Selected chemistries are highlighted on the display.



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(b) Using the Alpha Keys to Speed Select

Type the FIRST letter of the desired chemistry. This moves the cursor forward to the first chemistry that begins with the chosen letter. If this is the desired chemistry, press **SELECT**. If not, type the chosen letter again. This moves the cursor to the next chemistry that begins with the chosen letter. Subsequent pressing of the same letter advances the cursor to the next test in sequence (on that page of the display) beginning with that character. If there is more than one page of chemistry tests available, use PAGE DOWN to access them. Press SELECT to program the desired chemistry.

Pressing SELECT moves the cursor down to the next chemistry. Continue sample programming by 1) typing the FIRST letter of another chemistry, or 2) using the arrow keys to move the cursor to the desired chemistry. Press SELECT program the to desired chemistry.

1							
SAMPLE PROGRAI CONSOLE:	MMING			STANDBY STANDBY			May 25 95 12:52
<select> the</select>	desired	chemistrie	es. Pres	s <enter></enter>	when done.		(more)
Sector: Cup: Sample ID:	1 234567				Sample Type: Comment: Demographics:		
Panel:	6		Of	f-Line Di	lution Factor:	1.0	
	NA K CL CALC CO2 BUN3	CRE3 GLU3 TP3 UREA CA CREA	GLU ALT LD-L TBIL TG ALP	DBIL AST CK PHOS IRON ALB	CHOL MG GGT CKMB AMY URIC	DIG GENT TOBR METD COCM PHNY	
	ANUAL RDAC	SELECT CONTROL	STAT	CAROUSEL STATUS		NEXT AVI.	NEXT CUP
F1	F2	F3	F4	F5	F6	F7	F8
						A_(04149s.eps

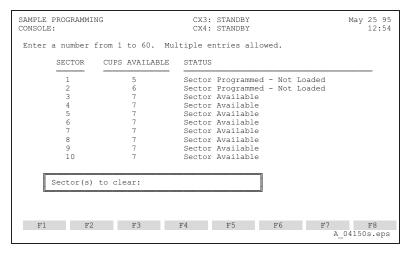
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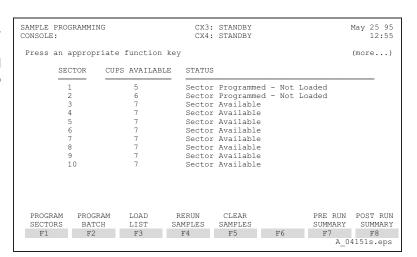
 When all selections have been made, press F7 NEXT AVL or F8 NEXT CUP to continue programming additional samples. Sample programs may be cleared by pressing F5 CLEAR SEC-TORS from the SAMPLE PROGRAM-MING Screen.

NOTE

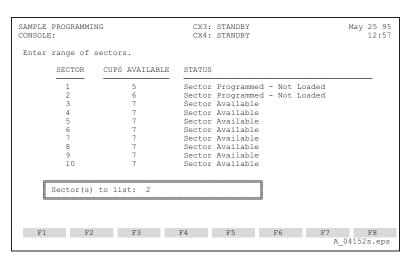
Cup number will increment automatically when F7 NEXT AVL is pressed, and will continue to the next available sector if necessary. Unavailable sectors are skipped. When the last cup within the sector is programmed, pressing F8 NEXT CUP will increment to the next cup in the sector for editing or programming. If all cups in the sector are programmed, pressing F8 will re-display the cup 1.

 When all programming is complete, press PREV SCREEN. For a summary of all programmed samples, press F3 LOAD LIST. (For detailed information on Load List, refer to Paragraph 6.4.5.)





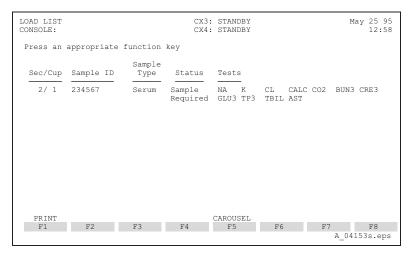
 Type the sector number(s) to be reviewed and press ENTER. Use the comma (,) or dash (-) keys to enter multiple sectors.



- Use PAGE UP and PAGE DOWN keys to view additional information.
- 11. Press **F1 PRINT** to obtain a hard copy of the report.
- 12. Press PREV SCREEN to return to the SECTOR STATUS Screen; or press F5 CAROUSEL to go to CAROUSEL STATUS Screen; or press MASTER SCREEN to exit.
- 13. Place programmed samples into the de-signated sector/cup positions.
- 14. Load sectors onto the autoloader as described in Paragraph 5.5.
- 15. When system is ready to process samples, press START from the MASTER Screen or the CAROUSEL STATUS Screen.

NOTE

Cup programming for these sectors may be modified until the sector has been loaded onto the sample wheel. Modifications allowed are shown in Table 6-10, Sector Status.



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6.4.2.2 Bar Code Mode

Sample programming provides the operator with a several functions: 1) assignment of a sample ID to each sample or control for processing, 2) entering specific information to characterize and identify the sample and its associated results, and 3) test selection and programming. Samples may be characterized through use of the SAMPLE COMMENT, SELECT CONTROL, SAMPLE TYPE and DILUTION FACTOR functions. Identification can be specified by entering PATIENT DEMOGRAPHICS. Sample programming allows the operator to optimize test selection by use of the PANELS (as defined by the operator in System Setup, Paragraph 6.5.1.2) and Manual ORDAC functions. In addition, samples can be designated as STAT for priority processing. The **STAT LOAD** button on the autoloader should be activated to expedite the loading of the STAT sample (refer to Paragraph 5.5.3).

- 1. From the MASTER Screen, press **F1 SAMPLE PROGRAM**.
- From the SAMPLE PROGRAMMING Screen, press F1 PROGRAM SAM-PLES.

WARNING

When creating Calibrator Bar Code IDs, use a format that distinctly differs from that used for sample IDs. This will prevent the reporting of erroneous results due to Calibrators being run as Patient Samples, or Patient Samples being run as Calibrators.

Examples:

Calibrator Bar Code ID: MULTICAL

Sample Bar Code ID: 0000001

NOTE

Pre-treated or pre-diluted cannot be programmed in the same sample program as regular tests (i.e., Immunoproteins and TP). These can be added as a rerun (refer to paragraph 6.4.4). When an error occurs in text selection that could potentially involve different sample types, the operator should clear the sample program (refer to paragraph 6.4.2.14) instead of deselecting and reselecting tests.

AMPLE PHONSOLE:	ROGRAMMING			(3: STANDBY (4: STANDBY			May 25 95 9:20
Press an	n appropriate	e function	n key				(more
			PROGRAMME	ED SAMPLES			
Queue	Sample ID	Sector	Cup Ti	me-Date Pro	grammed	Sample Sta	tus
62	581	58	1 -	12:33 - 19	/05	Complete	
58	571	57	1	11:14 - 18	/05	Complete	
57	561	56	1	12:55 - 17	/05	Complete	
55	553	55	3	13:13 - 16	/05	Complete	
54	552	55	2	13:02 - 16	/05	Complete	
53	551	55	1	15:03 - 15	/05	Complete	
44	187	18	7	18:17 - 05	/05	Complete	
43	186	18	6	18:16 - 05	/05	Complete	
42	185	18	5	18:16 - 05	/05	Complete	
41	184	18	4	18:16 - 05	/05	Complete	
40	183	18	3	18:15 - 05	/05	Complete	
39	182	18	2	18:15 - 05	/05	Complete	
PROGRAI	M PROGRAM	LOAD	RERUN	CLEAR	ASSIGN	PRE RUN	POST RUN
SAMPLES	BATCH	LIST	SAMPLES	SAMPLES	SEC/CUP	SUMMARY	SUMMARY
F1	F2	F3	F4	F5	F6	F7	F8

 The cursor is active at the Sample ID field. Type the sample ID to be programmed (up to 11 alphanumeric characters) and press ENTER.

NOTE

The instrument allows 2,000 sample ID's in queue at one time. When this limit is exceeded, the system will chronologically overwrite the oldest sample program. Duplicate sample ID's are not allowed. To clear sample ID's refer to Paragraph 6.4.2.13.

NOTE

Invalid Sample ID characters include *, ?, \$, space, comma and semi-colon. Alpha characters must be entered in upper case.

4. Sample Status is displayed beneath the chemistry selection area as an indicator of sample disposition in regard to testing. Possible status' are displayed in Table 6-12.

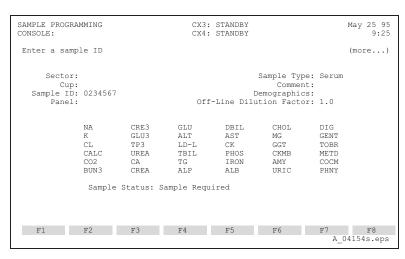
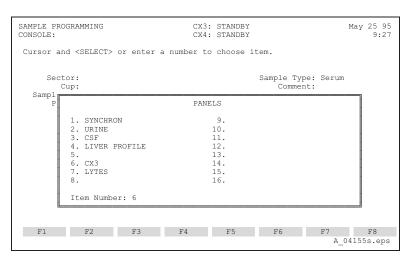


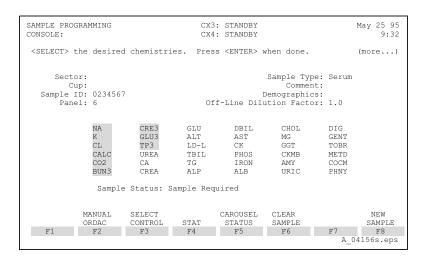
Table 6-12. Sample Status

Complete	All results are done, no pending tests remain No edits to sample program allowed unless sample is repeated using the Rerun feature
Incomplete	All results that can be performed are finished, but pending tests remain No edits to sample program allowed unless sample is repeated using the Rerun feature
Sample Required	Sample program is resident, system is waiting for the sample to be loaded Edits to the sample program may be made until the sample is loaded
Tests in Progress	Sample is being processed Tests can be added but not deleted; patient demographics can be modified
Removed	Tests are still in progress, but the sample has been removed from the sample carousel Can only modify patient demographics

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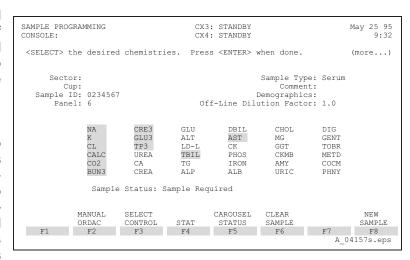
5. The cursor is active at the Panel input field. If programming using panels, press F1 SELECT OPTIONS to view and select from the list of previously defined panels, or enter the number directly (if known) at the Panel field (refer to Paragraph 6.5.1.2 for further details on defining panels). If programming individual tests, press ENTER or the down arrow to skip this field.





- Individual tests can be programmed from the chemistry selection area of the screen by cursoring to the desired test, or by using the alpha keys to locate and SELECT chemistries more quickly.
 - (a) Using the Cursor

Use the cursor control arrows to access the desired test. Press SELECT to program unassigned chemistries or to deprogram assigned chemistries. Continue to cursor and SELECT additional chemistries as desired. Selected chemistries are highlighted on the display.

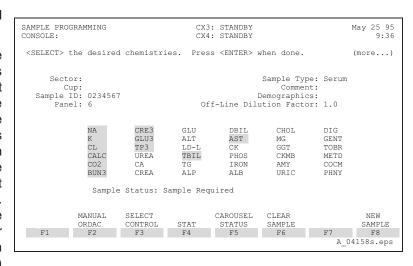


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(b) Using the Alpha Keys to Speed Select

> Type the FIRST letter of the desired chemistry. This moves the cursor forward to the first chemistry that begins with the chosen letter. If this is the desired chemistry, press **SELECT**. If not, type the chosen letter again. This moves the cursor to the next chemistry that begins with the chosen letter. Subsequent pressing of the same letter advances the cursor to the next test in sequence (on that page of the display) beginning with that character. If there is more than one page of chemistry tests available, use PAGE DOWN to access them. Press SELECT to program the desired chemistry.

> Pressing **SELECT** moves the cursor down to the next chemistry. Continue sample programming by 1) typing the **FIRST** letter of another chemistry, or 2) using the arrow keys to move the cursor to the desired chemistry. Press SELECT to program the desired chemistry.

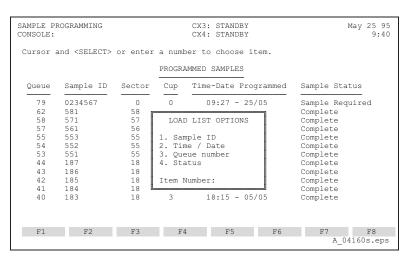


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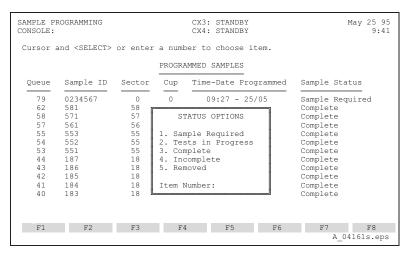
- 7. When all selections have been made, press F8 NEW SAMPLE to continue programming additional samples. Sample programs may be cleared by pressing F6 CLEAR SAMPLE, or by pressing F5 CLEAR SAMPLES from the SAMPLE PROGRAMMING Screen.
- 8. When all programming is complete, press **PREV SCREEN**.

SAMPLE PRO	OGRAMMING			3: STANDBY 4: STANDBY			May 25 95 9:38
Press an	appropriate	function	n key				(more
			PROGRAMME	D SAMPLES			
Queue	Sample ID	Sector	Cup Ti	me-Date Pro	grammed	Sample Sta	tus
79	0234567	0	0	09:27 - 25/	/05	Sample Req	uired
62	581	58	1	12:33 - 19/	/05	Complete	
58	571	57	1	11:14 - 18/	/05	Complete	
57	561	56	1	12:55 - 17/	/05	Complete	
55	553	55	3	13:13 - 16/	/05	Complete	
54	552	55	2	13:02 - 16/	/05	Complete	
53	551	55	2 1	15:03 - 15/	/05	Complete	
44	187	18	7	18:17 - 05/	/05	Complete	
43	186	18	6	18:16 - 05/	/05	Complete	
42	185	18	5	18:16 - 05/	/05	Complete	
41	184	18	4	18:16 - 05/	/05	Complete	
40	183	18	3	18:15 - 05/	/05	Complete	
PROGRAM	PROGRAM	LOAD	RERUN	CLEAR	ASSIGN	PRE RUN	POST RU
SAMPLES	BATCH	LIST	SAMPLES	SAMPLES	SEC/CUP	SUMMARY	SUMMAR
F1	F2	F3	F4	F5	F6	F7	F8
						A_0	4159s.ep

- For a summary of all programmed samples, press F3 LOAD LIST. (For detailed information on Load List, refer to Paragraph 6.4.5.)
- 10. Cursor and **SELECT** or type the number of the desired Load List option and press **ENTER**.



- 11. To call up load list by sample ID, time/ date, queue number, or sample status, enter the appropriate information at the prompt. If the status option was selected, cursor and SELECT or enter the status desired for Load List.
- 12. The Load List is displayed by the option selected. Use PAGE UP and PAGE DOWN keys to view additional information.
- 13. Press **F1 PRINT** to obtain a hard copy of the report.
- 14. Press PREV SCREEN to return to the QUEUE STATUS Screen; or press F5 CAROUSEL to go to the CAROUSEL STATUS Screen; or press MASTER SCREEN to exit.
- Place programmed samples into the appropriate sectors.
- 16. Load sectors onto the autoloader as described in Paragraph 5.5.
- When the system is ready to process samples, press START from the MASTER Screen or the CAROUSEL STATUS Screen.



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6.4.2.3 Assign Sector Cup/Manual Cup Assignment (Bar Code Mode only)

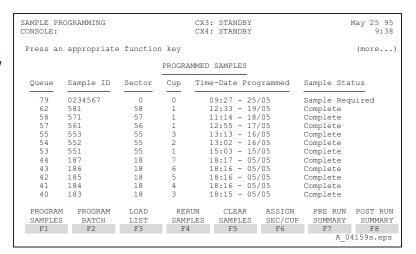
When running the instrument in bar code mode, an operator may assign a bar code ID to a sector/cup position in place of using a bar code label. A manual cup assignment is used when a bar code label is unavailable or unsuitable, or if the sample must be run in a cup. Multiple assignments may be made from the SAMPLE PROGRAMMING Screen. Manual bar code assignment from each screen is described below. Once the manual cup assignment is completed, the sector/cup will be displayed on the QUEUE STATUS Screen along with an "M" before the queue number.

WARNING

Prior to loading sectors for use in the bar code mode of operation or programming additional manual cup assignments, ALL manual cup assignments must be reviewed. Failure to clear lingering manual cup assignments could result in test results matched with inappropriate patient IDs and demographics.

Assign Sector/Cup - Making Multiple Cup Assignments

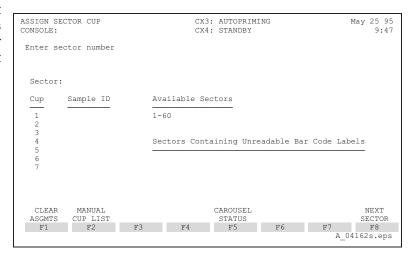
- 1. From the MASTER Screen, press **F1 PROGRAM SAMPLES**.
- From the SAMPLE PROGRAMMING Screen, press F6 ASSIGN SECTOR/ CUP.



 The cursor is active at the sector input field. Available sectors, as well as sectors containing unreadable bar code labels, are displayed on the right side of the screen.

NOTE

Only those sector numbers displayed are allowed as valid entries. Sectors displayed as "Available" contain at least one available cup position. "Sectors Containing Non Readable Bar Codes" contain at least one bar code label that cannot be read.



Type an available sector number from either group of sectors displayed and press ENTER.

WARNING

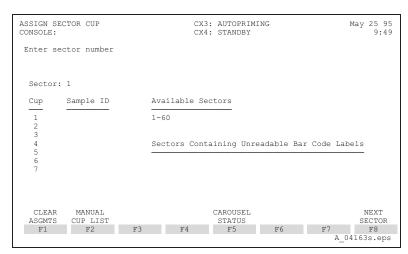
When creating Calibrator Bar Code IDs, use a format that distinctly differs from that used for sample IDs. This will prevent the reporting of erroneous results due to Calibrators being run as Patient Samples, or Patient Samples being run as Calibrators.

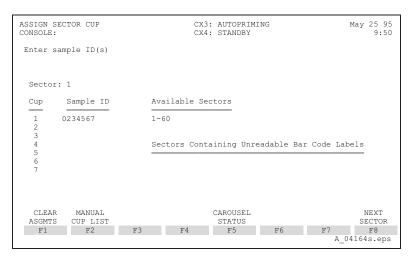
Examples:

Calibrator Bar Code ID: CXMULT

Sample Bar Code ID: 0000001

- 5. The cursor is active at the first available cup position. If the sector contains bar code IDs which have been successfully read, they are displayed in the appropriate cup positions. Cup positions which are empty or contain unreadable bar codes appear as blank input fields. Enter the bar code ID (Sample ID) to be manually assigned in the first available cup field.
- 6. Continue entering bar code IDs in blank cup fields as necessary. When all entries are complete for the sector displayed, press F8 NEXT SECTOR to continue making manual bar code assignments. To save the assignment and exit the display press PREV SCREEN to return to the QUEUE STATUS Screen, or press MASTER SCREEN to return to the MASTER Screen.
- 7. Print a Load List (refer to Paragraph 6.4.5) and load the samples into the appropriate sector/cup positions.

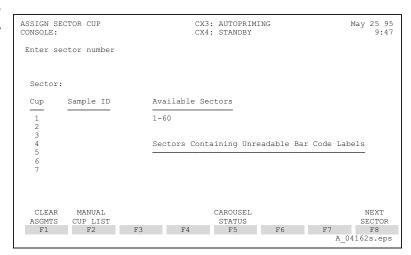




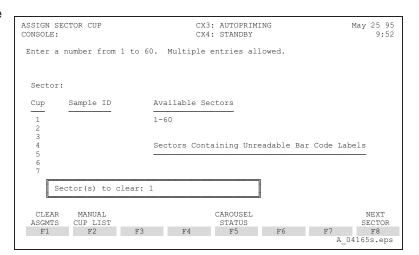
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Clearing Manual Cup Assignments

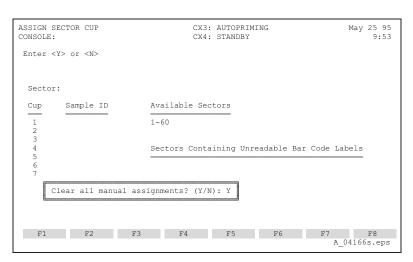
 From the ASSIGN SECTOR CUP Screen, press F1 CLEAR ASSIGN-MENTS.



2. Enter the sector number to be cleared. Multiple entries are allowed.



- At the confirm prompt, type Y and ENTER to clear all manual cup assignments for the sector entered, or type N and ENTER to cancel the clear request.
- Press PREV SCREEN to return to the SAMPLE PROGRAMMING Screen, or MASTER SCREEN to return to the MASTER Screen.



Important Notes Regarding Manual Cup Assignments

The following conditions apply to manual cup assignments:

- Operators MUST review all manual cup assignments prior to running, and MUST CLEAR all completed assignments or those which are no longer appropriate. There are several ways that a manual cup assignment can be cleared:
 - (a) The operator can manually clear manual cup assignments.
 - (b) If a sample program is cleared by the operator, all manual cup assignments associated with the sample program are cleared. This applies to unidirectional and bidirectional interfaced systems as well.
 - (c) Manual cup assignments for a sample program with Complete or Incomplete status may be cleared by the host when bidirectional communications are used to transmit sample programming.
 - (d) If the queue exceeds 2000, sample programs which contain manual cup assignments can be overwritten.

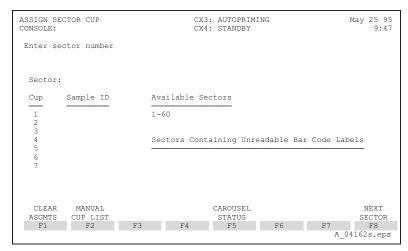
- 2. If a sector has a readable bar code and a manual cup assignment for the same sample position, the system will check to make sure that the bar code and the manual assignment match. If there is a discrepancy, the sample will not be processed and the operator notified with a displayed message. (The sector may be immediately off-loaded; or, all other correct bar code sample positions will be processed before off-loading. This option is defined by the operator in bar code setup.) If the bar code and the manual assignment agree, the sector remains on the carousel and is processed.
- 3. All manual cup assignments are lost when there is a switch to bar code mode.
- 4. If the rerun of a manual cup assignment is required, and Host Query is operational, it is possible that the programming for that cup may have already been cleared. This applies to sample programs with Complete or Incomplete status.
- Manual cup assignments are noted on the Master Screen and on the Sample Carousel Status Screen.
- Once manual cup assignments have been made, the Manual Cup Assignment Summary Report should be printed and the assignments verified.

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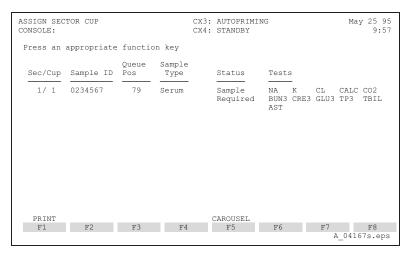
Manual Cup Assignment Load List

A load list for current manual cup assignments can be displayed and/or printed by the operator using a function key on the ASSIGN SECTOR CUP Screen.

- From the ASSIGN SECTOR CUP Screen, Press F2 MANUAL CUP LIST.
- Enter the sector(s) to be included in the load list. Multiple entries are allowed.



3. The load list includes the sector/cup assignment, sample ID (if entered), queue position, sample type, sample status and tests ordered for each manual cup assignment in the sector(s) requested. To print a hard copy of the manual cup assignment load list, press F1 PRINT. Press F5 CAROUSEL to go to CAROUSEL STATUS Screen.



6.4.2.4 Programming a Panel

A panel may be programmed from the Panel input field, or from the Select Panel window. Refer To paragraph 6.5.1.2 for defining panel in System Startup.

Option 1: From the Panel field

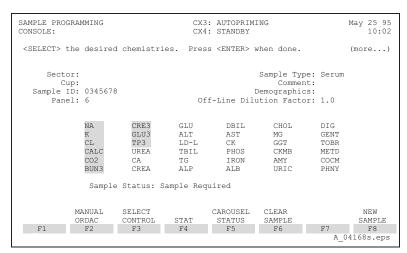
 On the SAMPLE PROGRAM Screen, when the cursor is active at the Panel field, enter the number of the panel desired as previously defined in System Setup. Multiple entries of panel numbers are allowed.

For example: Panel: 6

2. The tests within the panel entered will be selected and highlighted on the display. If individual chemistries other than those selected in the panel are desired, advance the cursor to the chemistry test field and use SELECT. Otherwise, press F7 NEXT AVL or F8 NEXT CUP in Sector/Cup mode to continue programming additional samples; in Bar Code mode, press F8 NEW SAMPLE to continue programming.

NOTE

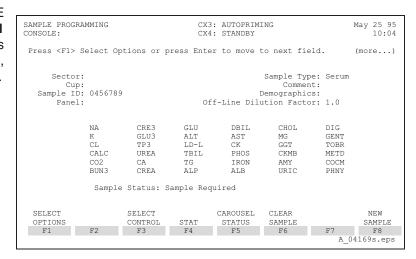
Individual tests within a panel may be deprogrammed by moving the cursor to the chemistry selection area and pressing **SELECT**. This does not alter the panel definition for subsequent sample programs.



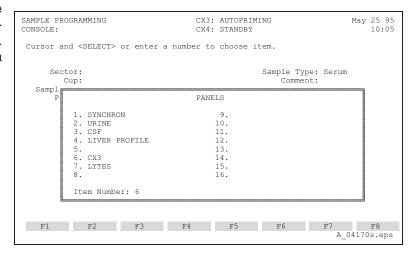
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Option 2: From the SELECT PANEL window:

 At the Panel field on the SAMPLE PROGRAM Screen, press F1 SELECT OPTIONS. If any panels have been defined in System Setup, the Select Panel window is displayed.



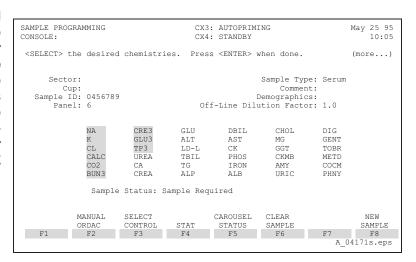
 Cursor and SELECT the panel to be programmed, or type the corresponding item number and press ENTER.
 Only one panel can be selected at a time from the window.



3. The tests within the panel entered will be selected and highlighted on the display. If individual chemistries other than those selected in the panel are desired, advance the cursor to the chemistry test field, otherwise press F7 NEXT AVL or F8 NEXT CUP in the Sector/Cup mode to continue programming additional samples; in Bar Code mode, press F8 NEW SAMPLE to continue programming samples.

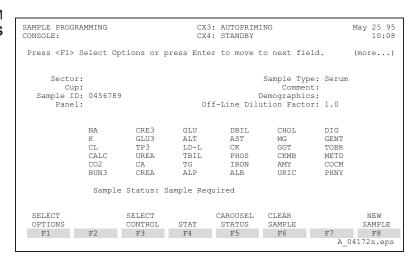
NOTE

Individual tests within a panel may be deprogrammed by moving the cursor to the chemistry selection area of the display and pressing **SELECT**. This does not alter panel definition for subsequent sample programs.

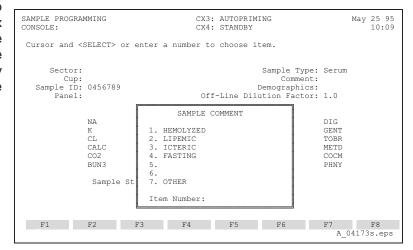


6.4.2.5 Entering a Sample Comment

 From the SAMPLE PROGRAM Screen, press F1 SELECT OPTIONS from the Comment field.



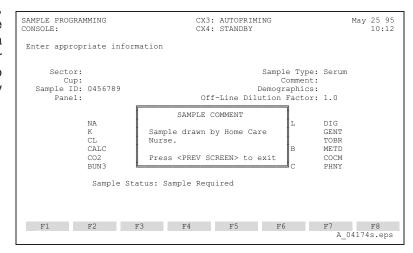
 A window prompts the operator to select a sample comment. Up to six pre-defined comments and one free text comment may be entered. The pre-defined comments are created by the operator in System Setup, Define Comments (Paragraph 6.5.1.12).



To enter a pre-defined comment, cursor and **SELECT** or enter the number of the comment. To create a comment, cursor and **SELECT** or enter the number for **OTHER**. Two lines (25 characters each) of text may be entered.

NOTE

Operators should note that sample comments are truncated after 11 characters on the Patient Multi-Sample report.



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- 3. Press PREV SCREEN when done.
- 4. The Comment field on the SAMPLE PROGRAM Screen will display Entered to indicate that a comment has been programmed.

SAMPLE PROGRAM CONSOLE:	MMING			: AUTOPRIN : STANDBY	MING	P	May 25 9 10:1
Press <f1> S</f1>	elect Op	tions or p	ress Enter	r to move	to next field		(more
Sector:					Sample Type:	Serum	
Cup:					Comment:	Entered	1
Sample ID:	0456789				Demographics:		
Panel:			Of	f-Line Di	lution Factor:	1.0	
	NA	CRE3	GLU	DBIL	CHOL	DIG	
	K	GLU3	ALT	AST	MG	GENT	
	CL	TP3	LD-L	CK	GGT	TOBR	
	CALC		TBIL			METD	
	CO2	CA	TG	IRON	AMY	COCM	
	BUN3	CREA	ALP	ALB	URIC	PHNY	
	Sample	Status: S	Sample Requ	uired			
SELECT		SELECT		CAROUSEL	CLEAR		NEW
OPTIONS		CONTROL	STAT	STATUS	SAMPLE		SAMPLE
F1	F2	F3	F4	F5	F6	F7	F8
						A 04	175s.ep

6.4.2.6 Entering Patient Demographics

 In the SAMPLE PROGRAM Screen, move the cursor to the Demographics field and press F1 SELECT OPTIONS.

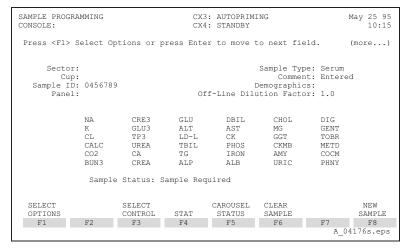
NOTE

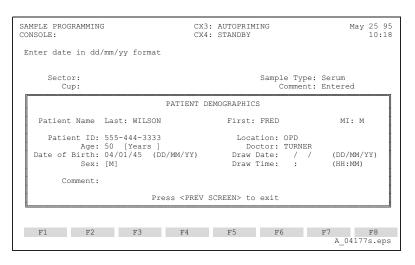
If the sample is already in progress on the sample carousel, press **ENTER** to move the cursor to the demographics field.

- 2. Enter the appropriate information within each field. (Refer to Table 6-13 for field lengths.)
- 3. When all desired demographics have been entered, press **PREV SCREEN** to close the window.

NOTE

The cursor will now be at the dilution factor field.





4. The Demographics field will display Entered to indicate that demographics have been defined. If CLEAR is pressed in the Demographic field, the field entry and all associated demographic information are cleared.

NOTE

If the operator enters patient demographics for a sample that is already on the lower wheel (carousel), the sample may not be run. This occurs because the operator accesses the sample program at the time the system tries to access the sample for test requirements. The status will be "Sample Required." Reload the sample to run.

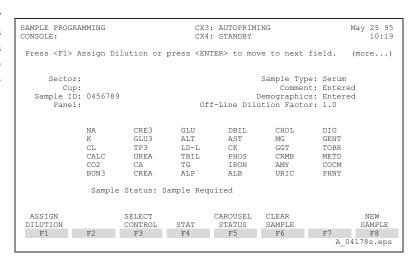


Table 6-13. Patient Demographics Field Input/Lengths

Demographic	Field Input/Length
Patient Name	Last (18) First (15) Middle Initial (1)
Patient ID	Up to 12 alphanumeric (12)
Age	0 to 175 (3)
Age Units	Hours, Days, Weeks, Months, Years [selectable]
Date of Birth	dd(1-31)/mm(1-12)/yy(0-99)
Sex	M or F (1) (Default is Male)
Location	20 alphanumeric
Doctor	18 alphanumeric
Draw Date	dd(1-31)/mm(1-12)/yy(0-99) or type c to default to current date
Draw Time	hh:mm or type c to default to current time
Comment	25 alphanumeric
	NOTE

If no default Reference Ranges have been selected by the operator, the report displays * - * in place of reference values when Age and Sex are not entered.

Entering a date of birth does not update the Age field. Reference range values are based on the Age field entry.

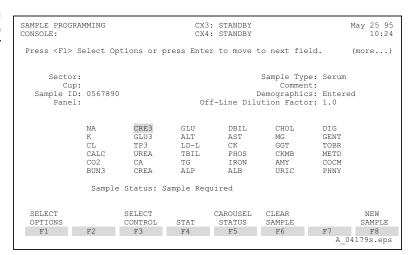
To default to current Draw Date and/or Draw Time, type c (lower case) when the cursor is in the appropriate field.

Patient ID is necessary for recall of the Patient Multi-sample Report, or in the event that a sample ID has been cleared and the operator wishes to use Results Recall.

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6.4.2.7 Changing the Sample Type

 In the SAMPLE PROGRAM Screen move the cursor to the Sample Type field and press F1 SELECT OPTIONS.



Move cursor to the desired sample type and press SELECT, or type the corresponding item number and press ENTER.

NOTE

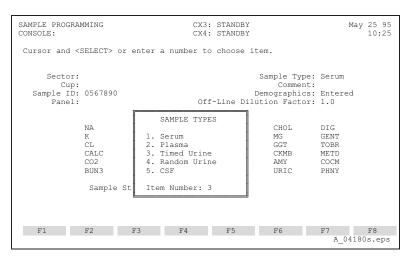
Serum is the default selection. If a control has been designated using **F3 SELECT CONTROL**, the sample type defined for the control will automatically be displayed.

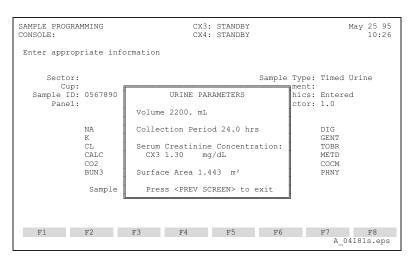
 The sample type selected will be displayed at the Sample Type field. If Timed Urine was selected, a second window will prompt the operator to enter additional sample information.

Additional sample information requested - for timed urines, CRE3, CREA, or CR-T selected:

- Volume
- · Collection period
- · Serum creatinine
- · Surface area

If CRE3 was selected, the operator is prompted to enter a serum CRE3 value. If CREA or CR-T was selected, the operator is prompted to enter a serum CREA or CR-T value. If both CRE3 and CREA/CR-T were selected, the default prompt requests the serum CRE3 value.





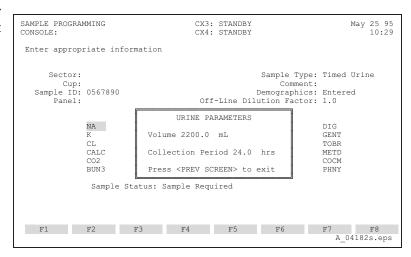
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Additional sample information requested - for timed urines, CRE3, CR-T, or CREA are not selected:

- Volume
- · Collection period

NOTE

A change of sample type is only applicable to the current cup or Sample ID. Subsequent sample programs will default to SERUM unless otherwise changed.



NOTE

When μ mol/L is the unit selected for either CREA, CRE3, or CR-T and Timed Urine or Random Urine is the sample type, the serum result is expressed in μ mol/L while the urine result is expressed in mmol/L. This complies with the international convention for reporting urine creatinine clearance.

NOTE

When creatinine is selected for a Timed urine sample, a Creatinine Clearance is automatically calculated if the Creatinine Clearance Special Calculation is enabled and the essential sample parameter information is input by the operator. The intended use of the triggered creatinine (CR-T) is to eliminate interference on serum samples. If CR-T is the only creatinine selected for a Timed Urine sample, operators are advised of the following:

- The serum CR-T value entered in the urine parameter window of the sample program will not appear on the printed report.
- Press PRINT SCREEN after entering the urine parameters to make a permanent record of the urine parameters window for the sample program.

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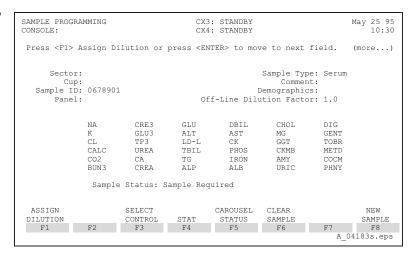
6.4.2.8 Entering a Dilution Factor

Operators may enter a dilution factor to be applied to the results of a specified sample program. The dilution factor represents an off-line dilution prepared by the operator, and may range from 1.0 to 1000.0. The default dilution factor is 1.0. Each result for the sample will be multiplied by the factor. Any final result generated by the system (to host, display or printed copy) has been multiplied by the factor. The dilution factor can be changed when programming a rerun. The dilution factor will be applied only to those chemistries selected for the rerun.

NOTE

Dilution factor and Manual ORDAC **cannot** be applied to a sample simultaneously. Dilution factor cannot be changed for a Rerun of a control.

- In the SAMPLE PROGRAM Screen, move the cursor to the Dilution field.
- 2. Press F1 ASSIGN DILUTION.



- 3. Enter a factor between 1.0 and 1000.0. Press **PREV SCREEN** to exit.
- Continue programming samples or press PREV SCREEN or MASTER SCREEN to exit.

NOTE

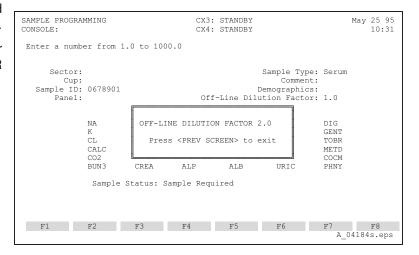
The dilution factor will be displayed for all chemistries on the results recall screen. All chemistries with a dilution factor other than 1.0 will be displayed in the Dilution field of the laboratory format reports.

Example: GLU 2.0 LDH: 3.0

The single patient multi-sample report will display parenthesis around the final result to which a dilution factor has been applied.

Example: GLU (680)

LDH (1245)



6.4.2.9 Programming a Manual ORDAC (Overrange Detection and Correction)

 The manual ORDAC feature is accessed from the SAMPLE PRO-GRAM Screen.

NOTE

The manual ORDAC feature allows the operator to ORDAC a sample the first time it is run (unlike chemistries selected for Automatic ORDAC (System Setup, Paragraph 6.5.1.8), which are run undiluted first and then rerun using ORDAC if recovery is out of range). This is helpful if the sample is expected to have results that are above the non-ORDAC-usable range.

In the chemistry test field, move cursor to the applicable test(s) and press
 F2 MANUAL ORDAC. This programs the test and marks it for ORDAC. The following tests have this feature:

ALP	BUN3	LDL	CKNa
ALT	GLU3	LDP	GOT
ALT-	URE3	PAMY	GPT
AST	CK	CKMB	HBDH
AST-	CK-	LAP	LDH
AMY	GGT	ALPd	

NOTE

All ORDAC results will be designated in the instrument code section on the results report. Sample programs with a Dilution Factor other than 1.0 cannot be programmed with manual ORDAC chemistries.

 Press F7 NEXT AVL or F8 NEXT CUP (Sector/Cup mode), or F8 NEW SAMPLE (Bar Code mode) to continue programming additional samples.

SAMPLE PROGRAMMING CONSOLE:			: STANDBY : STANDBY			May 25 95 10:33
<select> the desir</select>	ed chemistri	es. Pres	s <enter></enter>	when done.		(more)
Sector: Cup: Sample ID: 07890	12			Sample Type: Comment: Demographics:		
Panel:		Of	f-Line Di	lution Factor:		
NA K	CRE3 GLU3	GLU ALT	DBIL AST	CHOL MG	DIG GENT	
CL CALC	TP3 UREA	LD-L TBIL	CK PHOS	GGT CKMB	TOBR	
CO2 BUN3	CA CREA	TG ALP	IRON ALB	AMY URIC	COCM	
	le Status: S			ONIC	111141	
MANUAL ORDAC	SELECT CONTROL	STAT	CAROUSEL STATUS	CLEAR SAMPLE		NEW SAMPLE
F1 F2	F3	F4	F5	F6	F7	F8

SAMPLE PROGRAMMING	CX3	: STANDBY	May 25 95
CONSOLE:	CX4	: STANDBY	10:34
<select> the desired</select>	chemistries. Press	S <enter> when done.</enter>	(more)
			_
Sector: Cup:		Sample Type: Comment:	serum
Sample ID: 0789012		Demographics:	
Panel:	Of:	f-Line Dilution Factor:	1.0
NA	CRE3 GLU	DBIL CHOL	DIG
K	* GLU3 ALT	AST MG	GENT
CL	TP3 LD-L	CK GGT	TOBR
CALC			METD
CO2	CA TG		COCM
BUN3	CREA ALP	ALB URIC	PHNY
Sample	Status: Sample Requ	uired	
MANUAL	SELECT	CAROUSEL CLEAR	NEW
ORDAC	CONTROL STAT	STATUS SAMPLE	SAMPLE
F1 F2	F3 F4	F5 F6	F7 F8
			A_04186s.eps

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6.4.2.10 Programming a Control

The operator can set the system to program controls on CX4 chemistries by chemistry or by reagent cartridge though F5 QUALITY CONTROL from the MASTER Screen. In addition to programming controls for the CX3, if programming the CX4 quality control by chemistry, the system chooses the oldest on-board reagent cartridge when multiple cartridges of a given chemistry are residing on the system. Refer to paragraph 6.4.2.10.1 for programming by chemistry.

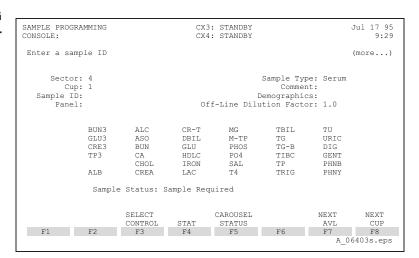
If programming the CX4 controls by reagent cartridge, the operator is given the option to choose which reagent cartridges to run in a QC sample program. Refer to paragraph 6.4.2.10.2 for programming by reagent cartridge.

In Bar Code Mode, the system defaults to the existing sample program for that bar code identification. If no sample program exists, the system automatically runs the chemistries defined for that bar coded control as setup through F5 QUALITY CONTROL. If the system is set to program by reagent cartridge, all reagent cartridges for those chemistries are run.

6.4.2.10.1 Programming a Control by Chemistry

6.4.2.10.1.1 Sector/Cup Mode

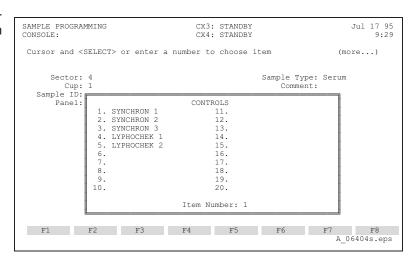
 From the SAMPLE PROGRAMMING Screen, press F3 SELECT CON-TROL at any active field.



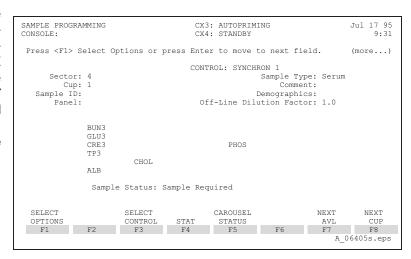
2. Cursor and **SELECT** the desired control, or type the corresponding item number and press **ENTER**.

NOTE

The controls are pre-defined by the operator in Quality Control, Define/Review. The control name, lot number, and sample type are automatically programmed when a control is selected and the associated results are compared to the defined ranges.



3. The control selected, along with the appropriate sample type and chemistries defined for that control is displayed on the SAMPLE PROGRAMMING Screen. In the Panel field, press F1 SELECT OPTIONS and SELECT the desired panel; or cursor to the chemistry. Tests for controls are selected in the same manner as patient samples. Refer to paragraph 6.4.2.

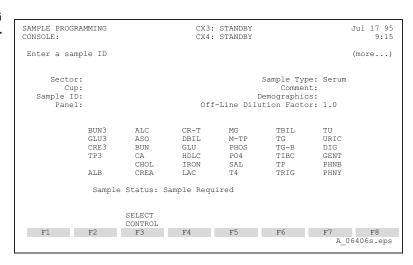


- If applicable, cursor to the Off-Line Dilution field and press F1 ASSIGN DILUTION. Type in the appropriate off-line dilution factor and press ENTER.
- Press F7 NEXT AVL or F8 NEXT CUP to continue programming additional samples.

6.4.2.10.1.2 Bar Code Mode

For a given bar coded control, the system defaults to the existing sample program for that bar code identification. If no sample program exists, the system automatically runs all chemistries defined for that bar coded control and resident on the system at the time of running. If duplicate cartridges of a chemistry exist, the system automatically runs the oldest on-board cartridge. The controls, chemistries and related bar codes are defined in Quality Control, Define/Review. To run select chemistries, the operator must set up a sample program.

 From the SAMPLE PROGRAMMING Screen, press F3 SELECT CON-TROL at the Sample ID field.

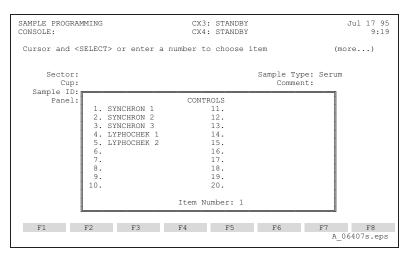


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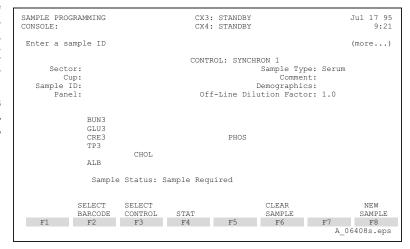
2. Cursor and **SELECT** the control applicable, or type the corresponding item number and press **ENTER**.

NOTE

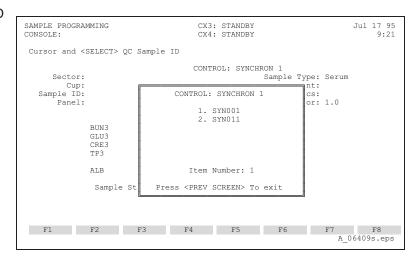
The controls are pre-defined by the operator in Quality Control, Define/Review. The control name, lot number, and sample type are automatically programmed when a control is selected and the associated results are compared to the defined ranges.



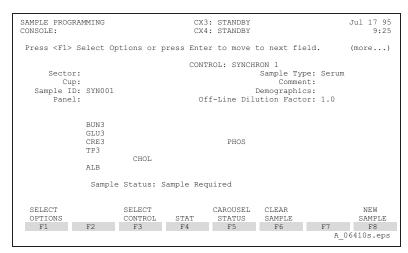
3. The control selected, along with the appropriate sample type and chemistries defined for that control is displayed on the SAMPLE PROGRAMMING Screen. The cursor will remain at the Sample ID field. Type in a sample ID and press ENTER, or press F2 SELECT BARCODE to select from previously defined bar codes for this control.



Cursor and SELECT the bar code ID desired.



- 5. In the Panel field, press **F1 SELECT OPTIONS** and **SELECT** the desired panel; or cursor to the chemistry. Tests for controls are selected in the same manner as patient samples. Refer to paragraph 6.4.2.
- If applicable, cursor to the Off-Line Dilution field and press F1 ASSIGN DILUTION. Type in the appropriate off-line dilution factor and press ENTER.
- 7. Press **F8 NEW SAMPLE** to continuing programming additional controls.



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6.4.2.10.2 Programming a Control by Reagent Cartridge

6.4.2.10.2.1 Sector/Cup Mode

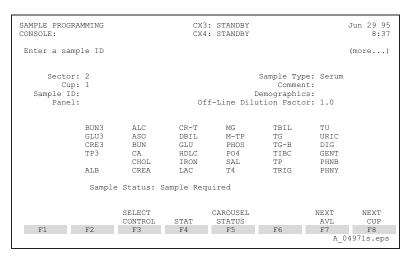
- From the SAMPLE PROGRAMMING Screen, press F3 SELECT CON-TROL at any active field.
- Cursor and SELECT the desired control, or type the corresponding item number and press ENTER.

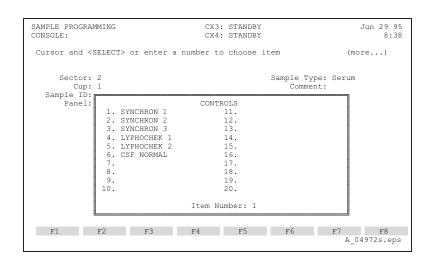
NOTE

The controls are pre-defined by the operator in Quality Control, Define/Review. The control name, lot number, and sample type are automatically programmed when a control is selected and the associated results are compared to the defined ranges.

WARNING

In Step 3 (below) DO NOT SELECT the panel number while in the PANELS window through F1 SELECT OPTIONS. The system will lock-up and rebooting. require operator may view the PANELS window as long as no selections are made while the window is open. PREV SCREEN out of the window and then enter the number while in the Panel field.





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3. The control selected, along with appropriate sample type is displayed. All on-board chemistry reagents defined in the QC database are displayed by position. In the Panel field, press F1 SELECT OPTIONS to view the desired panel; or cursor to the chemistry reagent positions and SELECT the reagent cartridge positions to include in the QC run.

NOTE

When selecting by a defined panel, the system selects **all** reagent cartridges for the chemistries defined for that panel and control. The operator can then cursor down and select or deselect reagent cartridge positions for the run.

- If applicable, cursor to the Off-Line Dilution field and press F1 ASSIGN DILUTION. Type in the appropriate off-line dilution factor and press ENTER.
- Press F7 NEXT AVL or F8 NEXT CUP to continue programming additional samples.

SAMPLE PROGRAMMING	CX3	: STANDBY			Jun	29 95
CONSOLE:	CX4	: STANDBY				8:39
Enter a sample ID					(mo	re)
	CONT	ROL: SYNCHRON 1				
Sector: 2		Samp	le Ty	pe: Seru	m	
Cup: 1		-	Comme	nt:		
Sample ID:		Democ	raphi	cs:		
Panel:	Of	f-Line Dilutior	Fact	or: 1.0		
1. ALB 7.	13.	19.	25.	BUN3	31.	CL
2. 8.	14.	20.	26.	GLU3	32.	CO2
3. PHOS 9.	15.	21.	27.	CRE3	33.	CALC
4. CHOL 10.	16.	22.	28.	TP3		
5. ALB 11.	17.	23.	29.	NA		
6. 12.	18.	24.	30.	K		
Sample	Status: Sample Req	uired				
	SELECT	CAROUSEL		NEXT		NEXT
	CONTROL STAT	STATUS		AVL		CUP
F1 F2	F3 F4		76	F7		F8
				A	0497	3s.eps

6.4.2.10.2.2 Bar Code Mode

For a given bar coded control, the system defaults to the existing sample program for that bar code identification. If no sample program exists, the system automatically runs **all** reagent cartridges for the chemistries defined for that bar coded control and resident on the system at the time of running. The controls, chemistries and related bar codes are defined in Quality Control, Define/Review. To run select reagent cartridge positions, the operator must set up a sample program.

 From the SAMPLE PROGRAMMING Screen, press F3 SELECT CON-TROL at the Sample ID field.

SAMPLE PROGRAM	MMING			STANDBY STANDBY			Jun 29 95 8:45
Enter a samp	le ID						(more)
Sector: Cup: Sample ID:					Sample Type: Comment: Demographics:	Serum	
Panel:			Of		ution Factor:	1.0	
	BUN3 GLU3 CRE3 TP3	ALC ASO BUN CA CHOL CREA	CR-T DBIL GLU HDLC IRON LAC	MG M-TP PHOS PO4 SAL T4	TBIL TG TG-B TIBC TP TRIG	TU URIC DIG GENT PHNB PHNY	
	Sample	Status: S	Sample Requ	iired			
		SELECT CONTROL					
F1	F2	F3	F4	F5	F6	F7 A_0	F8 14974s.eps

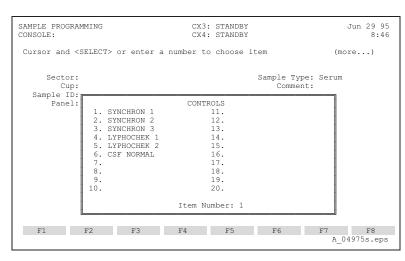
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2. Cursor and **SELECT** the control desired, or type the corresponding item number and press **ENTER**.

NOTE

The controls are pre-defined by the operator in Quality Control, Define/Review. The control name, lot number, and sample type are automatically programmed when a control is selected and the associated results are compared to the defined ranges.

3. The control selected, along with appropriate sample type is displayed. All on-board chemistry reagents defined in the QC database are displayed by position. Type in a sample ID and press ENTER, or press F2 SELECT BARCODE to select from previously defined bar codes for this control.

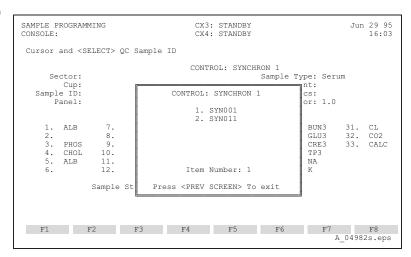


SAMPLE PROGRAMMING			STANDBY			Jun 29 95
CONSOLE:		CX4:	STANDBY			16:02
Enter a sample ID						(more)
		CONTR	OL: SYNCHE	RON 1		
Sector:				Sample Ty	pe: Ser	rum
Cup:				Comme		
Sample ID:			I	Demographi	cs:	
Panel:		Off	-Line Dil	ition Fact	or: 1.0)
1. ALB 7.		13.	19.	25.	BUN3	31. CL
2. 8.		14.	20.	26.	GLU3	32. CO2
 PHOS 9. 		15.	21.	27.	CRE3	33. CALC
4. CHOL 10.		16.	22.	28.	TP3	
5. ALB 11.		17.	23.			
6. 12.		18.	24.	30.	K	
Sample	Status:	Sample Requ	iired			
SELECT	SELECT			CLEAR		NEW
BARCODE	CONTROL	STAT		SAMPLE		SAMPLE
F1 F2	F3	F4	F5	F6	F7	F8
						A_04981s.eps

Cursor and SELECT the bar code ID desired.

WARNING

In Step 5 (below) DO NOT **SELECT** the panel number while in the PANELS window through SELECT OPTIONS. The system will lock-up and require rebooting. operator may view the PANELS window as long as no selections are made while the window is open. PREV SCREEN out of the window and then enter the number while in the Panel field.



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5. In the Panel field, press F1 SELECT OPTIONS to view the desired panel; or cursor to the chemistry reagent positions and SELECT the reagent cartridges/positions to include in the QC run.

NOTE

When selecting by a defined panel, the system selects **all** reagent cartridges for the chemistries defined for that panel and control. The operator can then cursor down and select or deselect reagent cartridge positions for the run.

- If applicable, cursor to the Off-Line Dilution field and press F1 ASSIGN DILUTION. Type in the appropriate off-line dilution factor and press ENTER.
- 7. Press **F8 NEW SAMPLE** to continuing programming additional controls.

SAMPLE PROGRAMMING CONSOLE:		: STANDBY : STANDBY		Jun 29 95 16:04
Press <f1> Select Op</f1>	tions or press Ente	r to move to nex	xt field.	(more)
Sector: 2 Cup: 1 Sample ID: SYN001 Panel:		- (le Type: Serum Comment: raphics: Factor: 1.0	ı
1. ALB 7. 2. 8. 3. PHOS 9. 4. CHOL 10. 5. ALB 11. 6. 12.	13. 14. 15. 16. 17. 18. Status: Sample Req	23.	25. BUN3 26. GLU3 27. CRE3 28. TP3 29. NA 30. K	31. CL 32. CO2 33. CALC
SELECT OPTIONS F1 F2	SELECT CONTROL STAT F3 F4	CAROUSEL CLEA STATUS SAMI F5 F6	PLE 6 F7	NEW SAMPLE F8 04983s.eps

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6.4.2.11 Programming a STAT Sample

6.4.2.11.1 Programming a STAT Sample (Sector/Cup Mode)

- From the SAMPLE PROGRAMMING Screen, press F1 PROGRAM SEC-TORS.
- 2. Type the sector number to be programmed and press **ENTER**.
- Enter the Sample ID (up to 11 alphanumeric characters). Sample ID is not a required field entry for sector/cup mode.

NOTE

Invalid Sample ID characters include *, ?, \$, space, comma, and semi-colon. Alpha characters must be entered in upper case.

 Press F4 STAT to program the sample as a STAT and activate the STAT mode.

NOTE

STAT is only active for the current cup or Sample ID being programmed.

- 5. If programming using panels, press F1 SELECT OPTIONS to view and select from the list of previously defined panels, or enter the number directly at the Panel field. If programming individual tests, press ENTER or the down arrow to skip the Panel entry field.
- If programming individual tests, cursor and SELECT the desired tests or use the alpha keys to locate and select tests.
- Press F7 NEXT AVL or F8 NEXT CUP to continue programming additional samples.
- 8. Press **MASTER SCREEN** when all programming is complete.
- 9. Place the STAT sample in the sector.
- Load the sector on the autoloader in the LOAD position.

SAMPLE PROGRAMMING CX3: STANDBY CX4: STANDBY <SELECT> the desired chemistries. Press <ENTER> when done. (more...) **STAT** Sector: 2 Sample Type: Serum Cup: 2 Sample ID: 456789 Demographics: Off-Line Dilution Factor: 1.0 Panel: 6 NA CRE3 GLU3 DBIL CHOL GENT ALT AST TP3 LD-L CK GGT TOBR CALC UREA TBIL PHOS CKMB METD TRON AMY COCM Sample Status: Sample Required CAROUSEL MANUAL SELECT NEXT NEXT STAT ORDAC CONTROL CIIP F4 F5 F2 F3 A 04187s.eps

- 11. Press the STAT LOAD button. This signals the microprocessor that the next sector to be loaded will be placed into the available STAT position on the sample carousel within the next possible load cycle.
- 12. If the system is not currently running, press the **START** key.

6.4.2.11.2 Programming a STAT Sample (Bar Code Mode)

- From the MASTER Screen, press F1 SAMPLE PROGRAM.
- From the SAMPLE PROGRAMMING Screen, press F1 PROGRAM SAM-PLES.
- Enter the Sample ID (up to 11 alphanumeric characters). Duplicate Sample IDs are not allowed.

NOTE

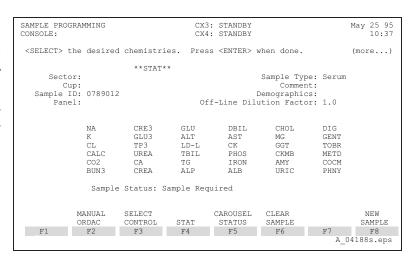
Invalid Sample ID characters include *, ?, \$, space, comma, and semicolon. Alpha characters must be entered in upper case.

 Press F4 STAT to program the sample as a STAT and activate the STAT mode.

NOTE

STAT is only active for the current cup or Sample ID being programmed.

- 5. If programming using panels, press F1 SELECT OPTIONS to view and select from the list of previously defined panels, or enter the number directly at the Panel field. If programming individual tests, press ENTER or the down arrow to skip the Panel entry field.
- If programming individual tests, cursor and SELECT the desired tests or use the alpha keys to locate and select individual tests.
- Press F8 NEW SAMPLE to continue programming additional samples.



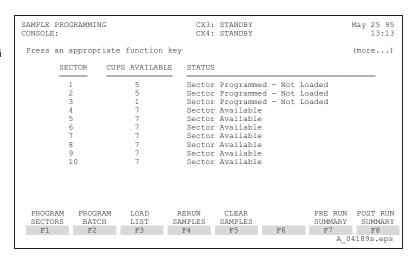
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- 8. Press **MASTER SCREEN** when all programming is complete.
- 9. Place the STAT sample in the sector.
- Load the sector on the autoloader in the LOAD position.
- 11. Press the STAT LOAD button. This signals the microprocessor that the next sector to be loaded will be placed into the available STAT position on the sample carousel within the next possible load cycle.
- If the system is not currently running, press the START key from the MAS-TER Screen or the CAROUSEL STA-TUS Screen.

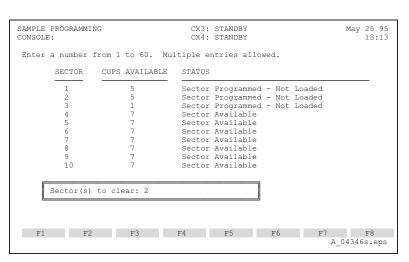
6.4.2.12 Clearing a Sector (Sector/Cup Mode only)

If all cups in a sector have been programmed and testing in complete, the sector is not available for further programming until it has been cleared. Only the programming information is deleted; the results are stored and are accessible through the recall function by the appropriate recall option (Paragraph 6.5.3).

- 1. From the MASTER Screen, press **F1 SAMPLE PROGRAM**.
- From the SAMPLE PROGRAMMING Screen, press F5 CLEAR SAMPLE.



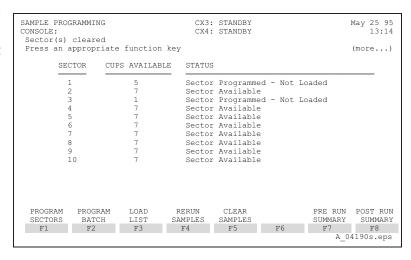
 Enter the number of the sector(s) to be cleared and press ENTER. Use the comma (,) or hyphen (-) key to enter multiple sectors.



- 4. The SAMPLE PROGRAMMING Screen will update the Status field.
- Press PREV SCREEN or MASTER SCREEN to exit.

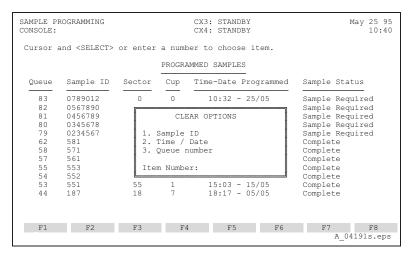
NOTE

All programming information will be lost when a sector is cleared; however, results are stored and may be recalled through the RECALL function (Paragraph 6.5.3).

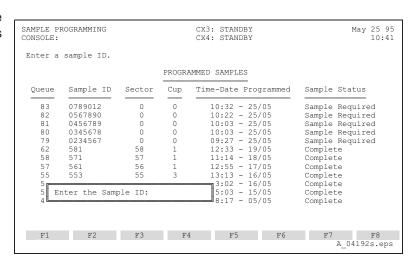


6.4.2.13 Clearing a Sample ID and Associated Programming (Bar Code Mode only)

- From the QUEUE STATUS Screen, press F5 CLEAR SAMPLES.
- Cursor and SELECT or type the item number of the clear option desired and press ENTER.

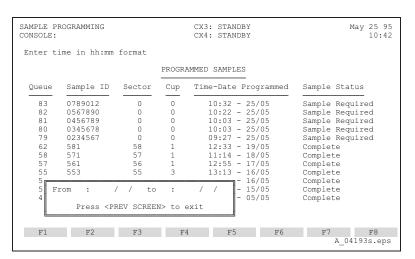


If item 1. Sample ID is selected, type the sample ID to be cleared and press ENTER.

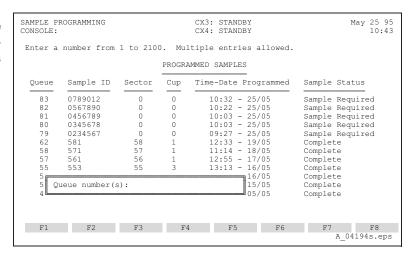


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4. If item 2. Time/Date is entered, type the start and end time/date range; this range refers to the date and time that the sample program was created.



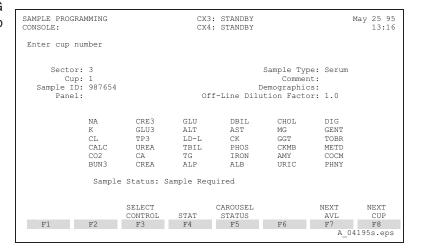
 If item 3. Queue Number is selected, type the Queue number(s) to be cleared and press ENTER. A message is displayed when the samples have been cleared.



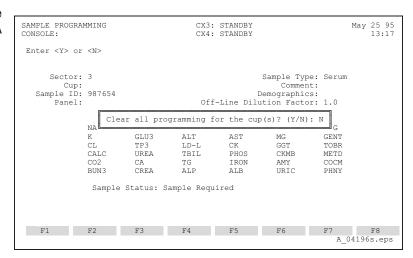
6.4.2.14 Clearing a Sample Program

6.4.2.14.1 Sector/Cup Mode

- From the SAMPLE PROGRAMMING Screen, move the cursor to the Cup field.
- 2. Press CLEAR.



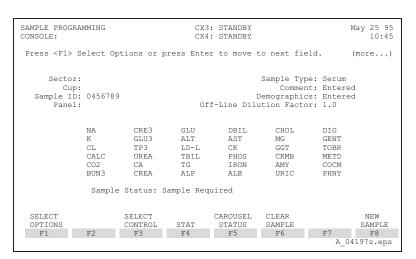
To clear the program displayed, type Y and press ENTER, at the prompt. A fresh screen will be displayed.



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6.4.2.14.2 Bar Code Mode

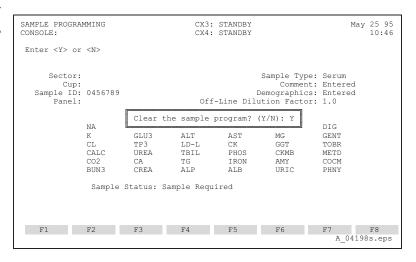
1. From the SAMPLE PROGRAM Screen, press **F6 CLEAR SAMPLE**.



To clear the program displayed type Y and press ENTER at the prompt. A fresh screen will be displayed.

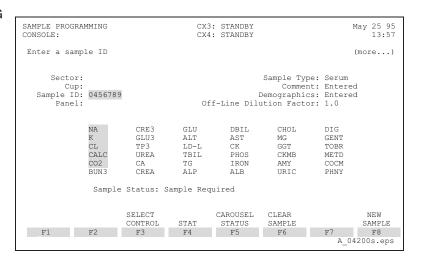
NOTE

Sample IDs must be unique. If the sample ID has been processed on the analyzer, it must be cleared for re-use. This is done from the QUEUE STATUS Screen using **F5 CLEAR SAM-PLE**.



6.4.2.15 Clearing a Sample ID from a Sample Program

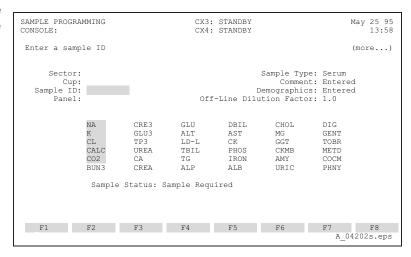
1. From the SAMPLE PROGRAMMING Screen, cursor to the Sample ID field.



Press CLEAR. The sample ID will be cleared from the field, and the sample program will remain displayed.

NOTE

In Bar Code mode, the program can be saved only if a Sample ID and at least one chemistry are entered. In Sector/Cup mode, the sector/cup assignment and at least one chemistry must remain to save the sample program.



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6.4.3 Batch Programming

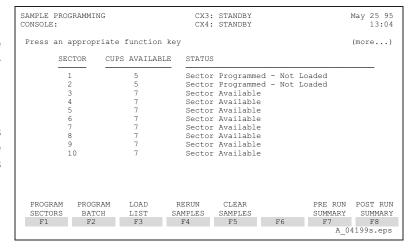
This feature allows programming of multiple samples with the same chemistries, sample type, dilution factor and status. A batch rerun option is detailed in paragraph 6.4.4.1.

6.4.3.1 Sector/Cup Mode

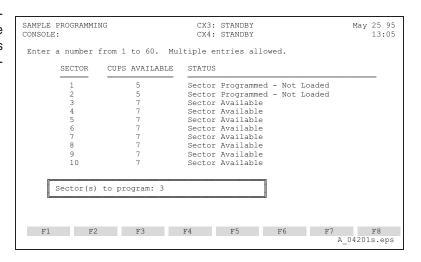
Sample identification and characterization of each cup may be individually entered later through the PROGRAM SECTOR function (Paragraph 6.4.2). The Batch Mode is deactivated when the next cup is accessed or upon exiting the SAMPLE PROGRAM Screen.

- 1. From the MASTER Screen, press **F1 SAMPLE PROGRAM**.
- Review the sector status to determine which sectors are available for programming. Press F2 PROGRAM BATCH.

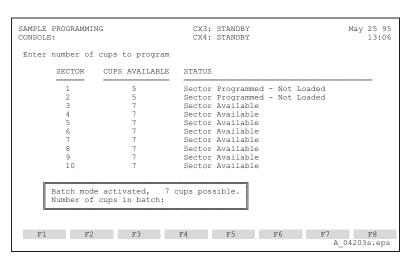
Each sector holds 7 cups or tubes. Assign a sufficient number of sectors to cover the number of samples in the batch. Partially programmed sectors may be used.



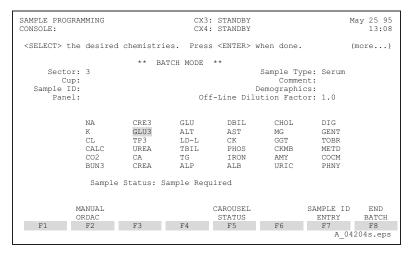
 Type the sector numbers to be programmed and press ENTER. Use the hyphen (-) key for sequential sectors or the comma (,) key for nonsequential sectors.

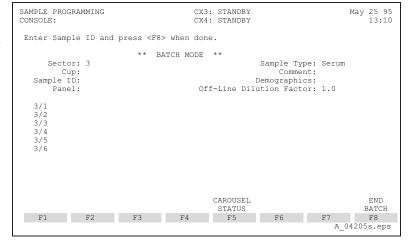


4. The number of cups displayed in the window is the maximum number of available cups which can be programmed within the sectors designated. Type the total number of cups to be batch-programmed and press ENTER.



- At the SAMPLE PROGRAMMING Screen, the cursor is active at the panel field. Sample information and test selection are programmed as for single cups (refer to Paragraph 6.4.2).
 - Any Panel, Comment, Demographics, Dilution Factor, Sample Type, or Chemistry programmed will apply to all sample cups designated within the batch. This information may be edited at any time on an individual cup basis once the batch mode is deactivated.
- 6. In the chemistry selection area, move cursor to the desired tests and press SELECT. To assign Sample IDs to each sector/cup, proceed with Step 7. If no Sample IDs are to be assigned, proceed with Step 9.
- 7. Press F7 SAMPLE ID ENTRY. The sectors and cups designated by the operator are displayed. Enter the Sample ID (if desired) for each sector/cup position. Press ENTER after each Sample ID entry. Up to 100 Sample ID's can be batch programmed.





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- To end Sample ID entry and to save the batch programming, press F8 END BATCH or F5 CAROUSEL STA-TUS.
- 9. Press **PREV SCREEN** or **MASTER SCREEN** to exit.

6.4.3.2 Bar Code Mode

 From the SAMPLE PROGRAMMING Screen, press F2 PROGRAM BATCH.

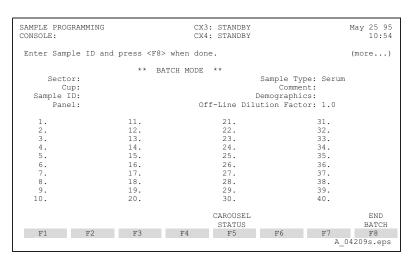
SAMPLE PROCONSOLE:	OGRAMMING			3: STANDBY 4: STANDBY			May 25 95 10:51
Press an	appropriate	e function	n key				(more)
			PROGRAMME	D SAMPLES			
Queue	Sample ID	Sector	Cup Ti	me-Date Pro	grammed	Sample Sta	tus
83	0789012	0	0	10:32 - 25/	/05	Sample Req	uired
82	0567890	0	0	10:22 - 25/	/05	Sample Req	
81	0456789	0	0	10:03 - 25/	/05	Sample Req	
80	0345678	0	0	10:03 - 25/	/05	Sample Req	
79	0234567	0	0	09:27 - 25/	/05	Sample Req	
62	581	58	1	12:33 - 19/	/05	Complete	
58	571	57	1	11:14 - 18/	/05	Complete	
57	561	56	1	12:55 - 17/	/05	Complete	
55	553	55	3	13:13 - 16/	/05	Complete	
54	552	55	2	13:02 - 16/	/05	Complete	
53	551	55	1	15:03 - 15/	/05	Complete	
44	187	18	7	18:17 - 05/	05	Complete	
PROGRAM	PROGRAM	LOAD	RERUN	CLEAR	ASSIGN	PRE RUN	POST RUN
SAMPLES	BATCH	LIST	SAMPLES	SAMPLES	SEC/CUP	SUMMARY	SUMMARY
F1	F2	F3	F4	F5	F6	F7	F8
						A_0	4207s.eps

 At the SAMPLE PROGRAMMING Screen, the cursor is active at the panel field. Enter the programming information for the batch (panels, individual chemistry selections, sample type, comment, and dilution factor).

Any Panel, Comment, Demographics, Dilution Factor, Sample Type, or Chemistry programmed will apply to all sample cups designated within the batch. This information may be edited at any time on an individual sample ID basis once the batch mode is deactivated.

 Press F7 SAMPLE ID ENTRY. Type the sample IDs (up to 100) to be included in the batch programming. Press ENTER after the last entry.

SAMPLE PROGRAMMING CONSOLE:		CX3: STA			М	ay 25 95 10:53
<select> the desired</select>	chemistries.	Press <ei< td=""><td>NTER> when</td><td>done.</td><td>(:</td><td>more)</td></ei<>	NTER> when	done.	(:	more)
	** BATCH	MODE **				
Sector: Cup: Sample ID:				ple Type: Comment: graphics:	Serum	
Panel:		Off-Li	ne Dilutio		1.0	
NA K				CHOL MG	DIG GENT	
CL				GGT	TOBR	
CALC				CKMB	METD	
CO2 BUN3				AMY URIC	COCM	
BUNS	CREA	ALP 1	ALB	URIC	PHNY	
Sample	Status: Samp	le Require	d			
MANUAL ORDAC					MPLE ID ENTRY	
F1 F2	F3	F4 1	F5	F6	F7	F8
					A_042	208s.eps



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 When all sample IDs have been entered, press F8 END BATCH. The display returns to the SAMPLE PRO-GRAMMING Screen; or press F5 CAROUSEL STATUS to enter CAR-OUSEL STATUS Screen.

SAMPLE PROGRAMMING CONSOLE:		CX3: STANDBY CX4: STANDBY		May 25 95 10:55
Enter Sample ID and	press <f8> when</f8>	done.		(more)
	** BATCH M	ODE **		
Sector:		S	ample Type: Seru	ım
Cup:			Comment:	
Sample ID:		De	mographics:	
Panel:			ion Factor: 1.0	
raner.		OII HINE DIIUC	ION FACCOL. I.U	
1. 0112345	11.	21.	31.	
2. 0122789	12.	22.	32.	
3. 0123579	13.	23.	33.	
4.	14.	24.	34.	
5.	15.	25.	35.	
6.	16.	26.	36.	
7.	17.	27.	37.	
8.	18.	28.	38.	
9.	19.	29.	39.	
10.	20.	30.	40.	
		50.	40.	
		CAROUSEL		END
		STATUS		BATCH
F1 F2	F3 F4	F5	F6 F7	F8
1.1	10 14	1.5		04210s.eps

6.4.4 Rerunning a Sample

This option allows the operator to reanalyze any test, sample or sector which has been completed and has valid results. The operator can also add tests, enter an off-line dilution factor and/or add a STAT indicator when programming a rerun. A batch rerun mode is available to either rerun certain tests for all samples or sectors selected, or to add new tests. Refer to paragraph 6.4.4.1 Rerunning a Completed Sample.

Operators may also add tests or program rerun of complete tests on samples that are currently on the lower sample wheel and are not marked for off-loading. However, no changes to the off-line dilution factor will be allowed. Refer to paragraph 6.4.4.2 Rerunning a Sample on the Lower Wheel (Carousel).

When the rerun is complete, the results obtained will overwrite existing results and the original results will no longer be available. A collated report of all results for the sample will be printed. A rerun indicator, (R), is printed next to the result on all laboratory formats and the recall screen. An instrument code, V, is printed along with the applicable chemistry code on all report formats.

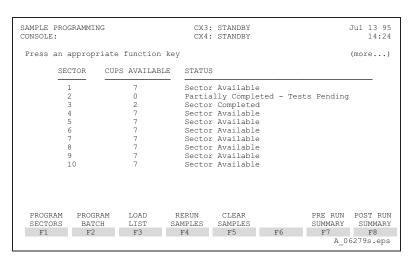
NOTE

If Result Approval For Host is enabled in System Setup, results must be sent/approved to the host, or cleared from pending host approval status, **F2 CLEAR STATUS**, in the approve function screen before programming a rerun.

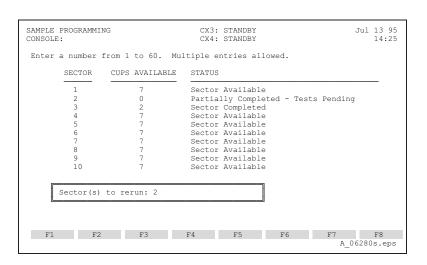
6.4.4.1 Rerunning a Completed Sample

6.4.4.1.1 Sector/Cup Mode

- 1. From the MASTER SCREEN, press F1 SAMPLE PROGRAM.
- From the SAMPLE PROGRAMMING Screen, press F4 RERUN SAMPLES.



3. Enter the sector(s) to be rerun.



 Cursor and SELECT the Rerun Option desired, or type the item number of the option and press ENTER.

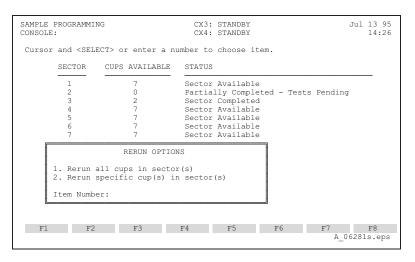
Option 1. Rerun all cups in sector(s).

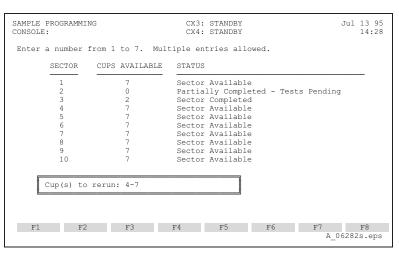
All cups originally programmed for the sector(s) are selected for rerun. Proceed to step 6.

Option 2. Rerun specific cup(s) in the sector(s).

Proceed to step 5 to select cups for rerun.

 Type in the cup(s) to be rerun and press ENTER. If multiple sectors are requested for rerun, type in the cup(s) for each sector, when prompted, and press ENTER.





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 Cursor and SELECT the rerun option for the sector and cup position(s) selected, or type the item number of the option and press ENTER.

Option 1. Rerun all tests.

All programmed tests are rerun for the sector(s) and cup(s) selected.

Option 2. Rerun specific tests.

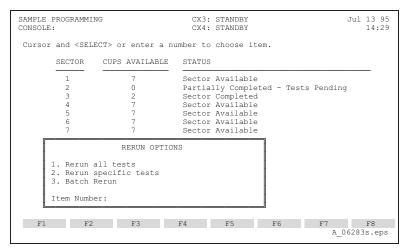
The sample program is retrieved for each of the sector(s) and cup(s) selected. The operator is allowed to add and delete tests, enter an off-line dilution factor and change the status to STAT as applicable. Proceed to step 7.

Option 3. Batch rerun

One sample program/chemistry menu screen is retrieved. The operator may select tests to be rerun on all sector(s) and cup(s) previously selected. Proceed to step 11.

CAUTION

When using Rerun to add a test that uses a pre-treated sample (e.g. TIBC, HDLc, IGA, IGG, IGM, TRF), it is recommended to use Option 3, Batch rerun or Option 2. Rerun specific tests. With Option 3, previously selected tests are automatically deselected and only the Batch rerun selected tests will be run using the pre-treated samples. When using Option 2, deselect previously run chemistries before selecting and running pre-treated samples. Failure to use Batch rerun or failure to deselect previously run chemistries using Option 2 will result in previously selected chemistries being rerun on the pre-treated sample.



7. Option 2. Rerun specific tests.

The sample program for the first selected sector/cup position is displayed. Cursor and **SELECT** to add and/or delete tests for rerun. **CLEAR** will deselect all tests.

SAMPLE PROGRAM CONSOLE:	MING		STANDBY STANDBY			Jul 13 95 15:37
<select> the</select>	desired chemi	stries. Press	<f8> when d</f8>	one.		(more)
Sector: Cup: Sample ID:	4			mple Type: Comment:	Serum	
Panel:		Off	-Line Diluti	on Factor:	1.0	
	BUN3 ALG GLU3 ASG CRE3 BU TP3 CA CHC ALB CRE Sample Statu	D DBIL N GLU HDLC DL IRON EA LAC	MG M-TP PHOS PO4 SAL T4	TBIL TG TG-B TIBC TP TRIG	TU URIC DIG GENT PHNB PHNY	
	NUAL DAC	STAT				NEXT CUP
	F2 F3	F4	F5	F6	F7	F8
					A_0	6284s.eps

 If applicable, cursor to the Dilution Factor field and press F1 ASSIGN DILUTION. Type in the off-line dilution factor to be used for the rerun test(s) for the sample and press ENTER.

NOTE

The dilution factor will be displayed for all chemistries on the results recall screen. All chemistries with a dilution factor other than 1.0 will be displayed in the Dilution field of the laboratory format reports.

Example: GLU: 2.0 LDH: 3.0

The single patient multi-sample report will display parentheses around the final result to which a dilution factor was applied.

Example: GLU (680) LDH (1245)

- 9. If applicable, press **F4 STAT** to assign a STAT priority to the sample.
- 10. When rerun programming is complete for the sample, press F8 NEXT CUP to continue rerun programming for the remaining sector(s)/cup(s). When all programming is complete press PREV SCREEN to return to the SAM-PLE PROGRAMMING Screen or MASTER SCREEN to return to the MASTER Screen.

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11. Option 3. Batch rerun. A single sample program screen is displayed. The cursor is active on the Panel field. Type in panel number or cursor to and SELECT tests to be rerun on all selected sector and cup position(s). If applicable enter an off-line dilution factor and/or apply STAT priority to all samples as described in steps 8 & 9. Press F8 END BATCH to complete the batch rerun programming; F5 CAROUSEL STATUS to enter the CAROUSEL STATUS Screen; or MASTER SCREEN to return to the MASTER Screen.

NOTE

Even though the load list (rerun status) will show all chemistries associated with the sample program, only the tests selected in rerun will be run.

6.4.4.1.2 Bar Code Mode

- 1. From the MASTER SCREEN, press F1 SAMPLE PROGRAM.
- From the SAMPLE PROGRAMMING Screen, press F4 RERUN SAMPLES.
- Cursor and SELECT the Rerun Option desired, or type the item number of the option and press ENTER.

Option 1. Sample ID(s).

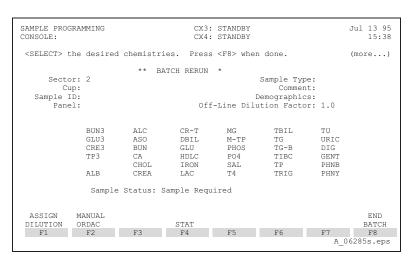
Proceed to step 4 to select Sample IDs.

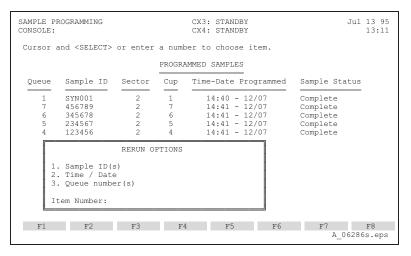
Option 2. Time/Date.

Proceed to step 5 to select time and date range.

Option 3. Queue number(s).

Proceed to step 6 to select queue numbers.



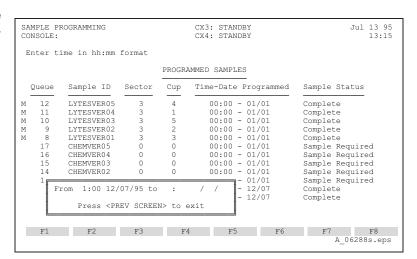


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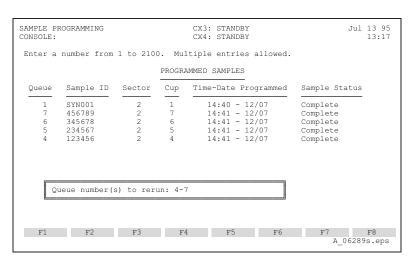
4. Rerun by Sample ID(s). Enter the sample ID(s) to be programmed for rerun. Press ENTER after each ID. When sample ID entry is complete, press F8 END SAMPL ID. Proceed to step 7.

SAMPLE PROGR	RAMMING				STANDBY STANDBY			Jul 13 95 13:12
Enter Sampl	e ID and	press <f8></f8>	when	done				(more)
1.123456	11.		21.		31.		41.	
2.234567	12.		22.		32.		42.	
3.345678	13.		23.		33.		43.	
4.	14.		24.		34.		44.	
5. 6.	15. 16.		25. 26.		35. 36.		45. 46.	
7.	17.		27.		36.		47.	
8.	18.		28.		38.		48.	
9.	19.		29.		39.		49.	
10.	20.		30.		40.		50.	
								END
								SAMPLID
F1	F2	F3	F4		F5	F6	F7	F8
							A 0	6287s.eps

 Rerun by Time/Date. Enter the time and date retrieval range for the sample rerun and press PREV SCREEN. Proceed to step 7.



Rerun by Queue number. Enter the Queue number(s) or range to be rerun. Proceed to step 7.



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 Cursor and SELECT the Rerun Option for the sample ID(s), time/date interval or queue number(s) previously selected, or enter the item number of the option and press ENTER.

Option 1. Rerun all tests.

All programmed tests are rerun for the sample ID(s), time/date interval or queue number(s) entered.

Option 2. Rerun specific tests.

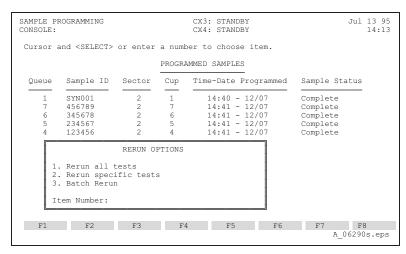
The sample program is retrieved for each of the sample ID(s), time/date interval or queue number(s) entered. The operator is allowed to add and delete tests, enter an off-line dilution factor and change the status to STAT as applicable. Proceed to step 8.

Option 3. Batch rerun.

One sample program/chemistry menu screen is retrieved. The operator may select tests to be rerun on all samples previously selected. Proceed to step 12.

CAUTION

When using Rerun to add a test that uses a pre-treated sample (e.g. TIBC, HDLc, IGA, IGG, IGM, TRF), it is recommended to use Option 3, Batch rerun or Option 2. Rerun specific tests. With Option 3, previously selected tests are automatically deselected and only the Batch rerun selected tests will be run using the pre-treated samples. When using Option 2, deselect previously run chemistries before selecting and running pre-treated samples. Failure to use Batch rerun or failure to deselect previously run chemistries using Option 2 will result in previously selected chemistries being rerun on the pre-treated sample.



 Option 2. Rerun specific tests. The sample program for the first selected sample is displayed. Cursor and SELECT to add and/or delete tests for rerun. CLEAR will deselect all tests.

1							
SAMPLE PROGRAM	MING			: STANDBY			Jul 13 95 14:18
CONSOLE.			CAH	. SIANDDI			14.10
<select> the</select>	desired	chemistri	es. Pres	s <f8> when</f8>	n done.		(more)
Sector: Cup: Sample ID:	4			,	Sample Type: Comment: Demographics:	Serum	
Panel:	123430		Of		ution Factor:	1.0	
	BUN3 GLU3 CRE3 TP3 ALB	ALC ASO BUN CA CHOL CREA	CR-T DBIL GLU HDLC IRON LAC	MG M-TP PHOS PO4 SAL T4	TBIL TG TG-B TIBC TP TRIG	TU URIC DIG GENT PHNB PHNY	
DILUTION OR	NUAL DAC F2	F3	STAT F4	F5	F6	F7	NEXT SAMPLE F8
		2.5	2.1	2.5	2.0		6291s.eps

 If applicable, cursor to the Dilution Factor field and press F1 ASSIGN DILUTION. Type in the off-line dilution factor to be used for the rerun test(s) for the sample and press ENTER.

NOTE

The dilution factor will be displayed for all chemistries on the results recall screen. All chemistries with a dilution factor other than 1.0 will be displayed in the Dilution field of the laboratory format reports.

Example: GLU: 2.0 LDH: 3.0

The single patient multi-sample report will display parentheses around the final result to which a dilution factor was applied.

Example: GLU (680)

LDH (1245)

- 10. If applicable, press **F4 STAT** to assign a STAT priority to the sample.
- 11. When rerun programming is complete for the sample, press F8 NEXT CUP to continue rerun programming for the remaining sector(s)/cup(s). When all programming is complete press PREV SCREEN to return to the SAM-PLE PROGRAMMING Screen or MASTER SCREEN to return to the MASTER Screen.

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12. Option 3. Batch rerun.

A single sample program screen is displayed. The cursor is active on the Panel field. Type in panel number or cursor to and SELECT tests to be rerun on all selected sector and cup position(s). If applicable enter an offline dilution factor and/or apply STAT priority to all samples as described in steps 9 & 10. Press F8 END BATCH complete the batch rerun programming; F5 **CAROUSEL** STATUS to enter the CAROUSEL STATUS Screen: or **MASTER SCREEN** to return to the MASTER Screen.

SAMPLE PROGRAMMIN	1G	CX3:	STANDBY			Jul 13 95
CONSOLE:		CX4:	STANDBY			14:19
<select> the des</select>	inad abamiatri	on Droom	ZEON rehon	dono		(more)
Carrell the des	sired Chemistri	.es. riess	<rp><ro> wilei</ro></rp>	done.		(more)
	** BA	ATCH RERUN	*			
Sector:				Sample Type:		
Cup:				Comment:		
Sample ID:				emographics:		
Panel:		Off-	-Line Dilu	tion Factor:	1.0	
BUN	N3 ALC	CR-T	MG	TBIL	TU	
GLU	J3 ASO	DBIL	M-TP	TG	URIC	
CRE		GLU	PHOS	TG-B	DIG	
TP3		HDLC	PO4	TIBC	GENT	
	CHOL	IRON	SAL	TP	PHNB	
ALE	B CREA	LAC	T4	TRIG	PHNY	
S a	ample Status: S	Sample Regui	ired			
50	mpre bedeus. e	Jampie Rega.	iica			
ASSIGN MANUA						END
DILUTION ORDAC		STAT	_		_	BATCH
F1 F2	F3	F4	F5	F6	F7	F8
					A_(16292s.eps

NOTE

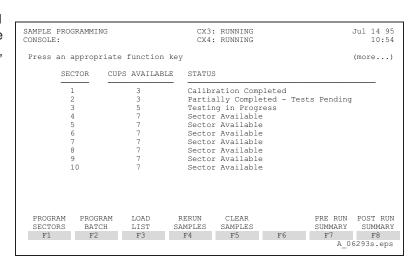
Even though, the load list (rerun status) will show all chemistries associated with the sample program, only the tests selected in rerun will be run.

6.4.4.2 Rerunning a Sample on the Lower Wheel (Carousel)

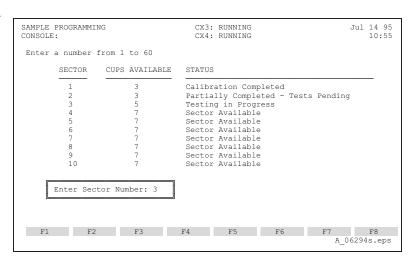
A rerun may be requested for any test with a status of "Complete" as long as the sample has not been marked for imminent off-loading from the lower sample wheel. Tests in progress may not be selected and the off-line dilution factor may not be changed. The operator may add new tests to the sample program. Rerun programming for samples still on the lower wheel is done through modification of the sample program, F1 PROGRAM SECTORS (or SAMPLES), not through F4 RERUN SAMPLES.

6.4.4.2.1 Sector/Cup Mode

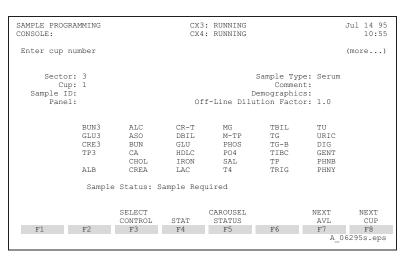
 From the MASTER Screen, press F1 SAMPLE PROGRAM. From the SAMPLE PROGRAMMING Screen, press F1 PROGRAM SECTORS.



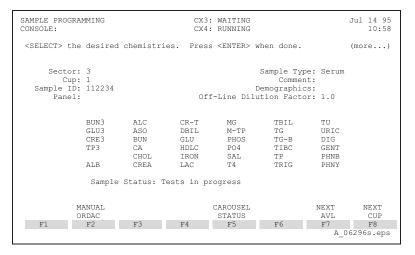
Type the sector number to be programmed for rerun and press ENTER.



3. Cursor to the cup field and type in the cup number and press **ENTER**.



- Cursor to and SELECT any completed test for rerun and/or any new test to be added to the sample program. Completed tests will have a red background.
- To continue programming sample reruns, press F8 NEXT CUP or cursor to the cup field and type in the cup number and press ENTER.
- To exit, press PREV SCREEN to return to the SAMPLE PROGRAM-MING Screen, or MASTER SCREEN to return to the MASTER Screen.



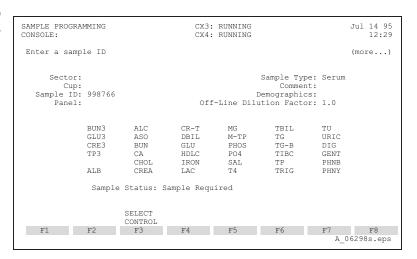
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6.4.4.2.2 Bar Code Mode

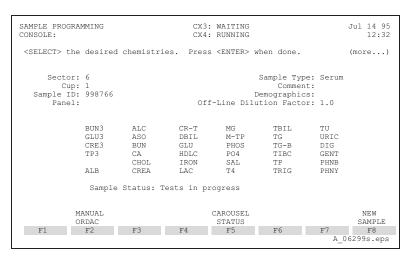
 From the MASTER Screen, press F1 SAMPLE PROGRAM. From the SAMPLE PROGRAMMING Screen, press F1 PROGRAM SAMPLES.

	AMPLE PRO	OGRAMMING			3: RUNNING 4: RUNNING			Jul 14 95 12:28
	Press an	appropriate	function	n key				(more)
				PROGRAMME	D SAMPLES			
	Queue	Sample ID	Sector	Cup Ti	me-Date Pro	grammed	Sample Sta	tus
M M	14 13	CHEMVER0 5 CHEMVER0 4 CHEMVER0 3 CHEMVER0 2 CHEMVER0 1 998766 887654 456789 345678 234567 223456	51 51 51 51 51 51 6 6 2 2 2 2 3	5 4 3 2 1 1 2 7 6 5 2 4	00:00 - 01, 00:00 - 01, 00:00 - 01, 00:00 - 01, 00:00 - 01, 12:26 - 14, 15:11 - 13, 15:11 - 13, 15:10 - 13,	/01 /01 /01 /01 /07 /07 /07 /07 /07 /07	Sample Req Sample Req Sample Req Sample Req Sample Req Tests in P Tests in P Complete Rerun Complete Rerun	uired uired uired uired rogress
	PROGRAM SAMPLES F1	PROGRAM BATCH F2	LOAD LIST F3	RERUN SAMPLES F4	CLEAR SAMPLES F5	ASSIGN SEC/CUP F6	PRE RUN SUMMARY F7	POST RUN SUMMARY F8
							A_0	6297s.eps

The cursor is active at the Sample ID field. Type the sample ID to be programmed for rerun and press ENTER.



- Cursor to and SELECT any completed test for rerun and/or any new test to be added to the sample program. Completed tests will have a red background.
- 4. To continue programming sample reruns, press F8 NEW SAMPLE or cursor to the Sample ID field and type in the Sample ID and press ENTER.
- To exit, press PREV SCREEN to return to the SAMPLE PROGRAM-MING Screen, or MASTER SCREEN to return to the MASTER Screen.



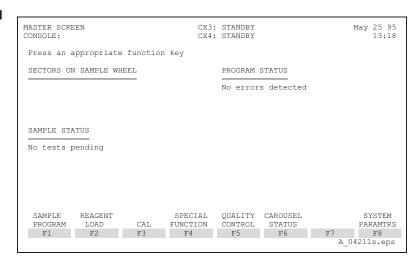
6.4.5 Load List

This option provides the operator with a listing of all programmed patient or control samples. Information includes sector and cup number, sample ID, sample type, sample status, and tests programmed.

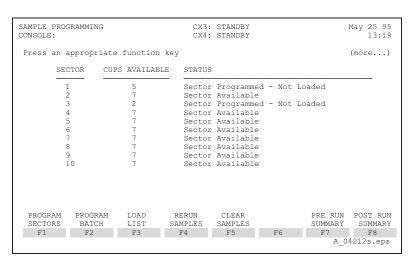
Reviewing the Load List

6.4.5.1 Sector/Cup Mode

 From the MASTER Screen, press F1 SAMPLE PROGRAM.



2. Press F3 LOAD LIST.

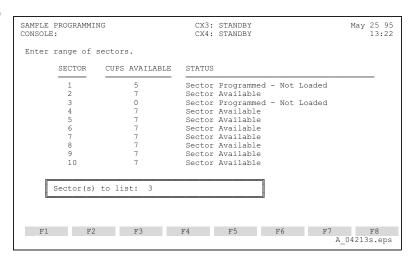


3. Enter the sectors to be listed (multiple entries allowed).

NOTE

Sample programs may exist which do not have sample ID assignments. For those sector/cup assignments, the sample ID field remains blank on the load list.

Calibrator samples with sector/ cup assignments can be listed using CAL LOAD LIST (refer to Paragraph 6.3.1).



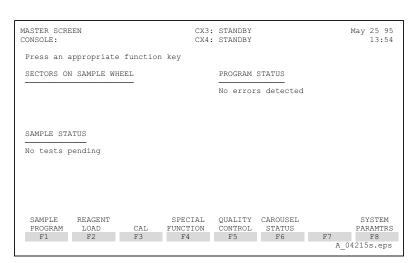
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4. Press **F1 PRINT** to obtain a hard copy of the load list.

LOAD LIST CONSOLE:				STANDBY STANDBY				M	ay 25 95 13:22
Press an	appropriate	function	key						
Sec/Cup	Sample ID	Sample Type	Status	Tests					
3/ 1	794321	Serum	Sample Required	NA K GLU3 TP3	CL	CALC	CO2	BUN3	CRE3
3/ 2	876544	Serum	Sample Required	GLU3					
3/ 3	789654	Serum	Sample Required	GLU3					
3/ 4	543786	Serum	Sample Required	GLU3					
3/ 5	102938	Serum	Sample Required	GLU3					
3/ 6	374650	Serum	Sample Required	GLU3					
3/ 7	845032	Serum	Sample Required	TBIL TG	CL UREA ALP	CALC CA	CO2 CREA		CRE3 LD-L
PRINT F1	F2	£3	F4	CAROUSEL F5	F6		F7		F8
F1	F2	F3	F4	F5	F6		F7	A_042	F8 214s.ep

6.4.5.2 Bar Code Mode

1. From the MASTER Screen, press **F1 SAMPLE PROGRAM**.



2. Press F3 LOAD LIST.

Proce an	SAMPLE PROGRAMMING CONSOLE:					May 25 95 10:57		
ricos an	appropriate	function	n key			(more.		
			PROGRAMMI	ED SAMPLES				
Queue	Sample ID	Sector	Cup Ti	ime-Date Pro	grammed	Sample Status		
83	0789012	0	0 -	10:32 - 25	/05	Sample Required		
82	0567890	0	0	10:22 - 25	/05	Sample Required		
81	0456789	0	0	10:03 - 25	/05	Sample Required		
80	0345678	0	0	10:03 - 25	/05	Sample Required		
79	0234567	0	0	09:27 - 25	/05	Sample Required		
86	0123579	0	0	10:52 - 25	/05	Sample Required		
85	0122789	0	0	10:52 - 25	/05	Sample Required		
84	0112345	0	0	10:52 - 25	/05	Sample Required		
62	581	58	1	12:33 - 19	/05	Complete		
58	571	57	1	11:14 - 18	/05	Complete		
57	561	56	1	12:55 - 17	/05	Complete		
55	553	55	3	13:13 - 16	/05	Complete		
PROGRAM	PROGRAM	LOAD	RERUN	CLEAR	ASSIGN	PRE RUN POST RU	UN	
SAMPLES	BATCH	LIST	SAMPLES	SAMPLES	SEC/CUP	SUMMARY SUMMAR	RΊ	
F1	F2	F3	F4	F5	F6	F7 F8		

 A window displays the Load List Options. Cursor and SELECT the option desired, or type the item number and press ENTER.

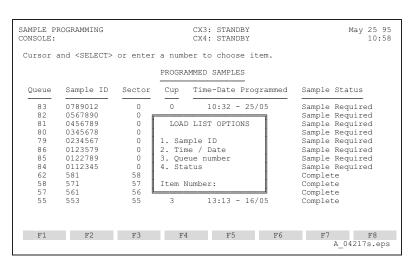
NOTE

In Bar Code mode, no sector/ cup assignments are made until the samples are read at the sample bar code reader. Unless manual cup assignments have been made, the sector/cup assignments on the load list will be blank for samples run in bar code mode.

Only calibrator samples with manual cup assignments (refer to Paragraph 6.3.1.3) are included in this load list.

(a) Load List by Sample ID

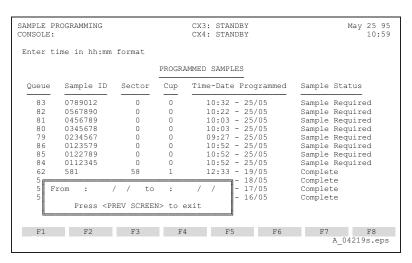
Enter the Sample ID to be listed. The Load List is displayed. Press **F1 PRINT** to obtain a hard copy of the list.



MPLE P	ROGRAMMING			CX3: STANDBY CX4: STANDBY	May 25 9 10:5		
nter a	sample ID.						
			PROGRA	AMMED SAMPLES			
Queue	Sample ID	Sector	Cup	Time-Date Programmed	Sample Status		
83	0789012	0	0	10:32 - 25/05	Sample Required		
82	0567890	0	0	10:22 - 25/05	Sample Required		
81	0456789	0	0	10:03 - 25/05	Sample Required		
80	0345678	0	0	10:03 - 25/05	Sample Required		
79	0234567	0	0	09:27 - 25/05	Sample Required		
86	0123579	0	0	10:52 - 25/05	Sample Required		
85	0122789	0	0	10:52 - 25/05	Sample Required		
84	0112345	0	0	10:52 - 25/05	Sample Required		
62	581	58	1	12:33 - 19/05	Complete		
5				1:14 - 18/05	Complete		
	nter the Samp	ple ID:		2:55 - 17/05	Complete		
5 🖳				3:13 - 16/05	Complete		
F1	F2	F3	F	4 F5 F6	F7 F8		
L I	F Z	13	r.	01 (1 P	A 04218s.ep		

(b) Load List by Time/Date Programs Created

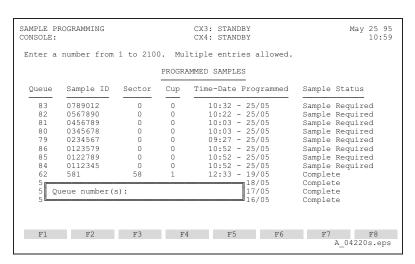
Enter the time and date range for the load list. Enter a time/date beyond the latest time/date required to make sure all requested samples are listed. The Load List is displayed. Press **F1 PRINT** to obtain a hard copy of the list.



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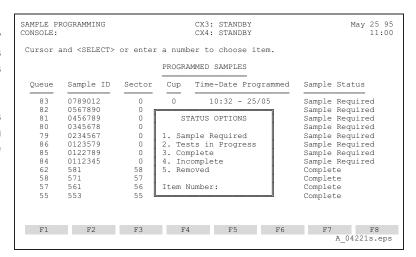
(c) Load List by Queue Number(s)

Enter the queue number(s) to be listed. The Load List is displayed. Press **F1 PRINT** to obtain a hard copy of the list.

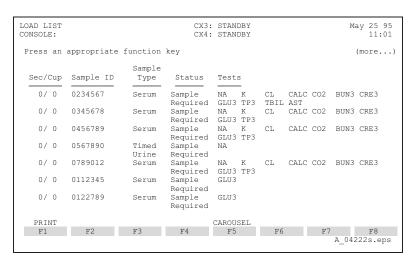


(d) Load List by Status

A load list can be retrieved by sample status. Status groupings include Sample Required, Tests in Progress, Complete, Incomplete, and Removed. Cursor and **SELECT** the status option desired, or type the item number and press **ENTER**. The load list is displayed.



 Press F1 PRINT to obtain a hard copy of the list. Press F5 CAROUSEL to go to CAROUSEL STATUS Screen.



6.4.6 Pre-Run Summary Report

This feature provides the operator with a printed report listing CX4 reagent name and location, number of tests available per cartridge, the reagent status and the calibration status. In addition, CX4 resident and non-resident test summaries are printed. For CX3 chemistries, the report provides the total tests programmed, reagent status, and calibration status. CX3 electrolyte reagent status provides the % volume and status for electrolyte buffer, electrolyte reference, and CO2 acid and CO2 alkaline reagents. The number of tests indicated on the Pre-Run Summary report does not include any reagent usage due to automatic ORDAC function.

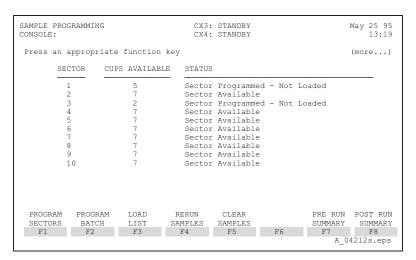
Reviewing the Pre-Run Summary Report

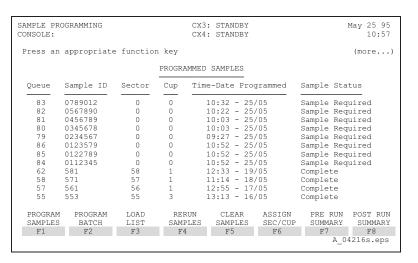
- From the MASTER Screen, press F1 SAMPLE PROGRAM.
- Press F7 PRE RUN SUMMARY. This summary report will automatically be printed when F7 key is pressed. (Refer to Appendix E for an example report.)

NOTE

A slight delay may occur after **F7** is pressed as the programming database is being accessed. Do not press repeatedly.

 Press PREV SCREEN or MASTER SCREEN to return to the MASTER Screen.





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6.4.7 Post-Run Summary Report

This option provides a printed list of the samples that are pending or incomplete, and an explanation of the status. Incomplete or pending tests are generated due to a reagent or calibration situation. To rerun a pending test simply reload the sector or bar coded tube. Results for tests rerun replace previous results and are collated into the existing reported tests in the sample.

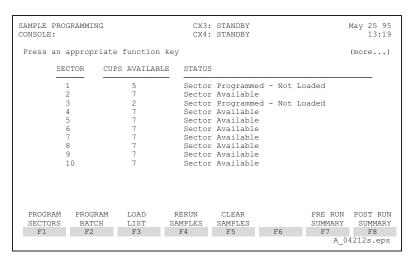
Reviewing the Post-Run Summary Report

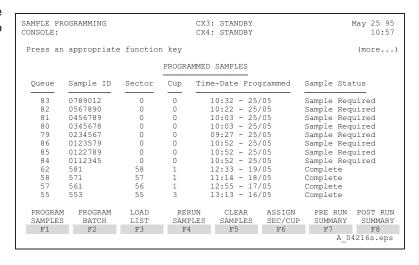
- From the MASTER Screen, press F1 SAMPLE PROGRAM.
- Press F8 POST RUN SUMMARY.
 The summary report will be automatically printed when F8 is pressed.
 (Refer to Appendix E for an example report.)

NOTE

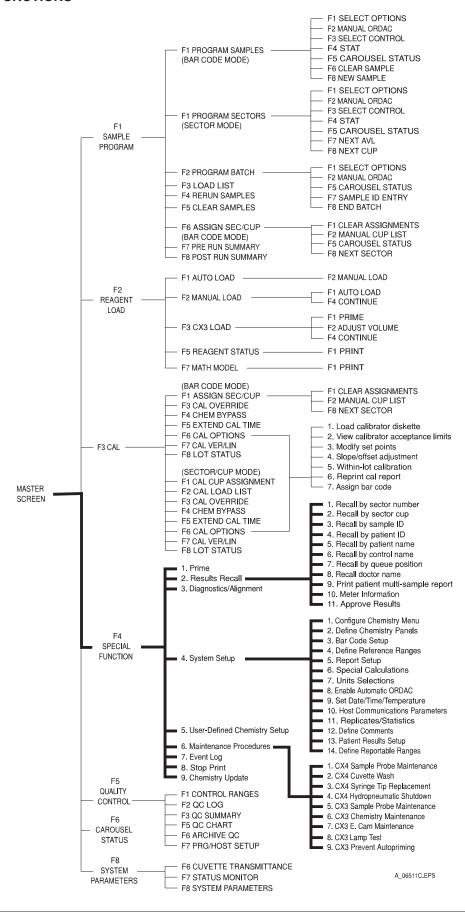
A slight delay may occur after **F8** is pressed as the databases are being accessed. Do not press repeatedly.

Press the PREV SCREEN key or the MASTER SCREEN key to return to the MASTER Screen.





6.5 SPECIAL FUNCTIONS



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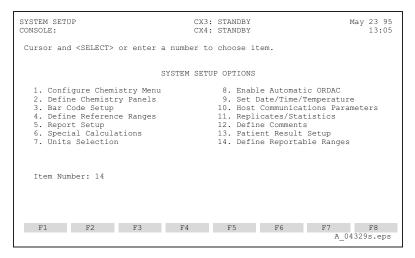
6.5.1 System Setup

6.5.1.1 Chemistry Menu Configuration

This option allows the operator to select from a comprehensive list of the available tests only those applicable to the user laboratory. Of the total tests available, 72 chemistries can be installed onto the menu at one time. For optimal speed of sample programming, this menu can be customized to mirror the test order on the lab request forms. The Chemistry Menu Configuration screen may be viewed at any time, but modifications can only be made when the system is in Standby.

Configuring the Chemistry Menu

- From the MASTER Screen, press F4 SPECIAL FUNCTION.
- Cursor and SELECT 4. System Setup, or type 4 ENTER.
- 3. Cursor and **SELECT 1**. Configure Chemistry Menu, or type **1 ENTER**.



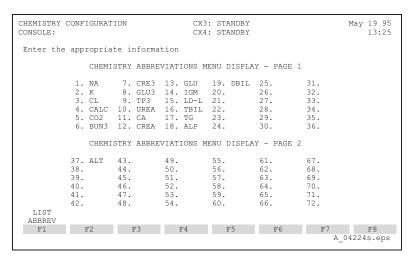
 Press F1 LIST ABBREV to generate a printed comprehensive listing of the available tests and the appropriate test abbreviations (refer to Figure 6-7).

NOTE

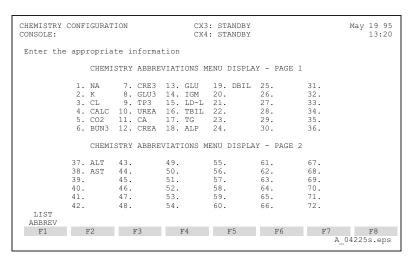
Only those chemistries which appear on the list can be installed. The user-defined chemistries must be defined prior to installation in order to be listed. (Refer to Paragraph 8.2 for the user-defined setup procedure.)

BUN and UREA both display as available chemistries; only one may be configured at a time.

BUN3 and URE3 both display as available chemistries; only one may be configured at a time.



5. The menu is divided into two groups of 36 chemistries each, designated as Page 1 and Page 2 (refers to how the chemistries are displayed throughout the system). Move cursor (with the arrow keys) to the desired position on the menu and enter the test name to be installed.



NOTE

The installed test name must be spelled as shown in the list of chemistry name abbreviations. The same test name cannot be used more than once.

CX3 chemistries (CX7 users only) are permanently configured on the system. These chemistries may be relocated on the configuration screen, but not removed.

BUN3 and URE3 occupy the same position on the menu. To replace one chemistry with other, overwrite the existing chemistry abbreviation with the replacement abbreviation. Only one, BUN3 or URE3, may be configured at any one time.

Either BUN or UREA may be configured on the CX4, but not both. To replace BUN with UREA, or vice versa, clear the existing chemistry abbreviation, then enter the other abbreviation.

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SYNCHRON CX7 DELTA

ABBREVIATION OF DEFINED CHEMISTRIES

	Chemistrie	-	User Chemistries	
ALB	GGT	TG-B	CHO	
ALC	GLU	THC	GLUG	
ALP	GLU3	THC5		
ALFd	GOT	THEO		
ALT	GPT	TIBC		
ALT-	HBDH	TOBR		
AMM 	HDLC	TP		
AMPH	IGA	TP3		
AMY	IGG	TRF		
ASO	IGM	TRIG		
AST	IRON	TU		
AST-	K	URE3		
BARB	LAC	UREA		
BENZ	LAP	URIC		
BUN	LD-L			
BUN3	LD-P			
DA	LDH			
CHE	LIPA			
CHOL.	M-TP			
DK	METD			
CK-	METQ			
CKMB	MG			
CKNa	NA			
CL 505	OP.			
C0S	PAMY			
COCM	PCP			
CR-T	PHNB			
CRE3 CREA	PHNY			
	PHOS			
DRP CALC	P04			
DBIL	SAL T4			
DIG	TBIL			
GENT	TG			

Figure 6-7. Defined Chemistries

- Repeat Step 5 until all applicable chemistries are placed in the desired positions. Any positions left blank will be reflected on all menu displays.
- Press PREV SCREEN to return to the SYSTEM SETUP Screen, or press MASTER SCREEN to exit.

Clearing a Menu Position

1. From the CHEMISTRY CONFIGURATION Screen, move cursor to the chemistry to be removed from the menu and press CLEAR or type over an existing test name with a new name. It is not necessary to deconfigure a chemistry before moving it to another position, although it must be moved to a vacant position.

NOTE

Chemistries which currently have reagent cartridges on board, are included in any pending or requested sample programs, or which are part of a control definition cannot be cleared. CX3 chemistries are permanently installed because they are considered always on-board, and cannot be cleared. Clearing a test from the chemistry menu will remove it from all applicable programming screens. However, any existing data for that test will be accessible from the recall function.

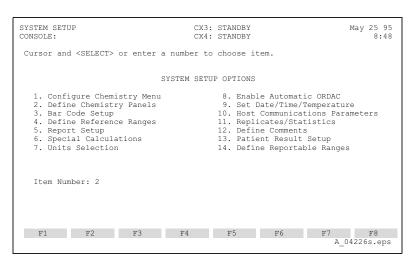
2. Press PREV SCREEN to return to the SYSTEM SETUP Screen, or press MASTER SCREEN to exit.

6.5.1.2 Panel Definition

This option allows the user to group tests that are commonly ordered together into panels. These groups, or panels, may then be used to expedite sample programming by selecting the panel number, which then automatically programs all chemistries associated with that panel. Up to 16 panels can be defined. Panel Definition can be modified at any time.

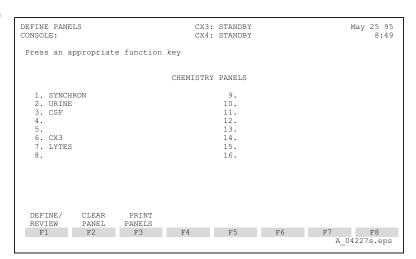
Defining Chemistry Panels

- From the MASTER Screen, press F4 SPECIAL FUNCTION.
- 2. Cursor and **SELECT 4**. System Setup, or type **4 ENTER**.
- 3. Cursor and **SELECT 2**. Define Chemistry Panels, or type **2 ENTER**.

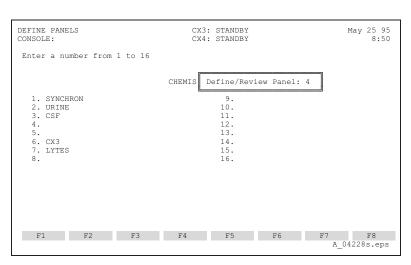


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 All currently defined panels (if any) are displayed. To define a new panel, press F1 DEFINE/REVIEW.



5. Type the number of the panel to be defined and press **ENTER**.

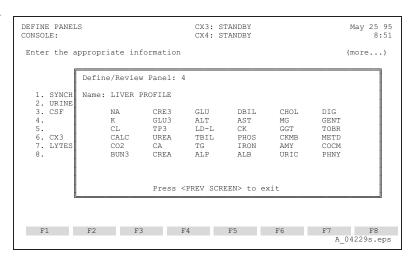


Enter a panel name of up to 25 characters.

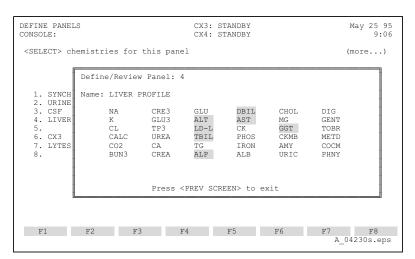
For example: LIVER PROFILE

NOTE

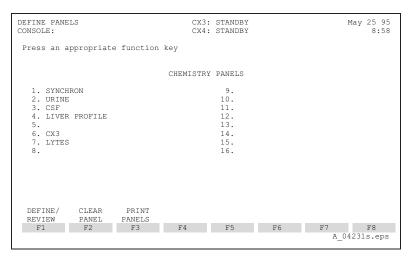
If no name is designated, the name defaults to PANEL # after the chemistries have been defined. For example PANEL 4.



Move cursor to the chemistries to be included in the panel and press SELECT to mark.



- Press PREV SCREEN to close the window.
- 9. Repeat Steps 4 through 8 until all desired panels have been defined.
- Press F3 PRINT PANELS to obtain a hard-copy summary of all defined panels (refer to Figure 6-8).
- 11. Press **PREV SCREEN** to return to the SYSTEM SETUP Screen, or press **MASTER SCREEN** to exit.



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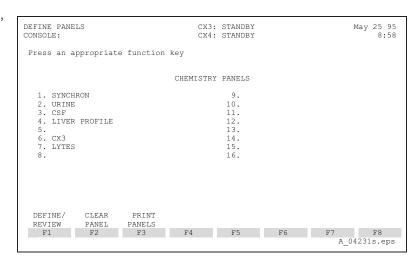
CX7 DELTA CHEMISTRY PANELS

PANEL	NAME	CHEMISTRIES			
1	SYNCHRON	CO2, CALC, BUN3, GLU3, CRE3, DBIL, TBIL, TG, K, CL, NA, TP3, ALP, ALT, LD-L, AST, CK, GGT, PHOS, ALB, IRON, MG, CHOL, URIC			
2	URINE	CALC, GLU3, CRE3, K, CL, NA			
3	CSF	GLU3, CL, TP3			
4	LIVER PROFILE	DBIL, TBIL, ALP, ALT, LD-L, AST, GGT, LAP			
5					
6	CX3	CO2, CALC, BUN3, GLU3, CRE3, K, CL, NA, TP3			
7	LYTES	CO2, K, CL, NA			
е					
9					
10					
11					
12					
13					
14					
15					
16		A_05081C.EPS			

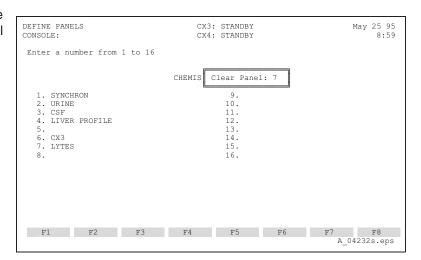
Figure 6-8. Chemistry Panels

Clearing a Panel

1. From the DEFINE PANELS Screen, press **F2 CLEAR PANEL**.



2. Type the number of the panel to be cleared and press **ENTER**. The panel name is cleared from the display.



3. Press **PREV SCREEN** to return to the SYSTEM SETUP Screen, or press **MASTER SCREEN** to exit.

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6.5.1.3 Bar Code Setup

Bar Code Setup option allows the operator to enable or disable the bar code reader, enable or disable various bar code types, modify configuration parameters specific to each bar code type, assign sample IDs when transitioning from sector/cup mode to bar code mode, and to make sector/cup assignments when transitioning from bar code mode to sector/cup mode. In addition, the operator can select to immediately offload sectors with unreadable bar code labels, or to process the samples with readable bar codes on the sector. Bar Code Setup can be viewed at any time, but modifications may only be made when the system is in Standby.

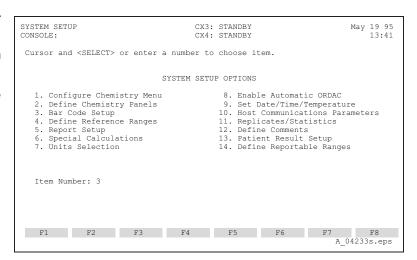
NOTE

When transitioning from bar code mode to sector mode and vice versa, calibrations Requested and Assigned will return to a status of Calibration Requested. In sector mode, operators should reassign sector/cups with Cal Cup Assignment. In bar code mode, confirm all calibrator bar code IDs and reselect chemistries for calibration.

When transitioning modes of operation, do not press **HOME** or **STOP** Keys.

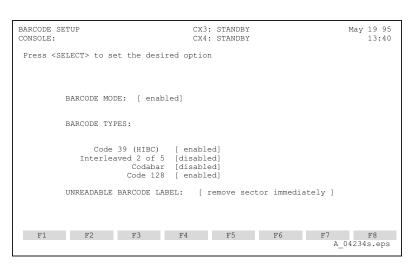
Enable/Disable Bar Code Mode

- 1. From the MASTER Screen, press **F4 SPECIAL FUNCTION**.
- 2. Cursor and **SELECT 4**. System Setup, or type **4 ENTER**.
- Cursor and SELECT 3. Bar Code Setup, or type 3 ENTER.

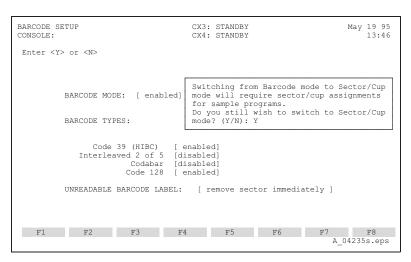


 The cursor is active at the Bar Code Mode field. Use SELECT to toggle between [enabled] and [disabled]; the default mode is Bar Code Mode enabled.

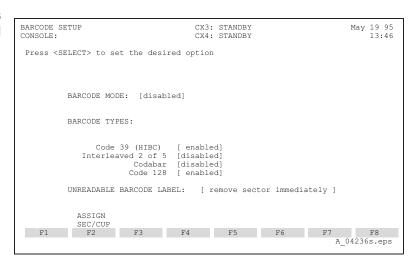
If calibration assignments and/or sample program requests exist, sample identification needs to be addressed. If switching from bar code mode to sector/cup mode, continue with Step 5. If switching from sector/cup mode to bar code mode, proceed to Step 8.



If calibration assignments and/or sample program requests exist, the operator is prompted to confirm switching from Barcode mode to Sector/Cup mode. Type Y and press ENTER to confirm, or N and press ENTER to cancel.



Verify that the Bar Code Mode is [disabled]. Press **F2 ASSIGN SECTOR/CUP**.

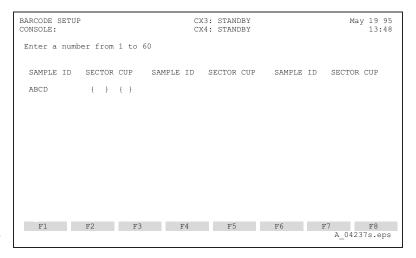


6. The sample IDs with sample program requests or calibration requests are displayed on the screen, sorted in ascending order. Enter a sector number and press **ENTER**, then enter a cup number and press **ENTER**. Continue to enter sector/cup assignments for the sample IDs to be processed in sector/cup mode. Duplicate sector/cup assignments are not allowed.

NOTE

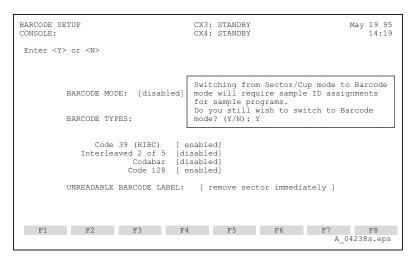
All levels of a calibrator type must reside in the same sector.

 Press PREV SCREEN to save sector/ cup assignments and return to the main BAR CODE SETUP Screen.

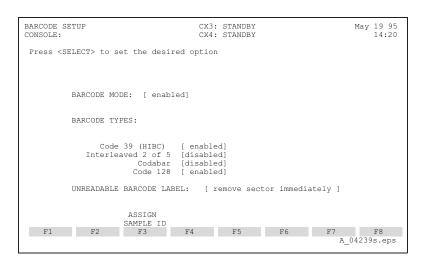


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 If switching from sector/cup mode to bar code mode, use SELECT to enable Bar-code Mode. Type Y to confirm switching to Barcode mode, or N to cancel.



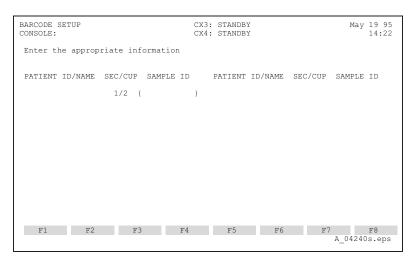
9. Press F3 ASSIGN SAMPLE ID.



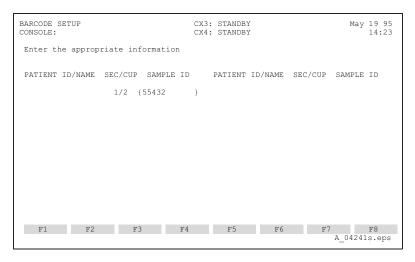
 Sample program requests or calibration requests with existing sector/cup assignments are displayed with the patient name or patient ID.

NOTE

Sample IDs must be assigned to sample programs with sector/ cup assignments before leaving BAR CODE SETUP. Exiting without making Sample ID assignments will delete the sample programs.



- 11. Enter a Sample ID of up to 11 alphanumeric characters. Duplicate sample IDs are not allowed. Continue entering sample IDs for all samples to be processed in bar code mode.
- Press PREV SCREEN to save the sample ID assignments and return to the main BAR CODE SETUP Screen.



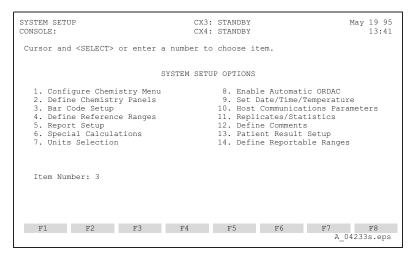
Enable/Disable Bar Code Types (Bar Code Mode Only)

This function is useful only if the Bar Code Mode is enabled. If Bar Code Mode is disabled, none of the Bar Code types are read by the analyzer.

Four bar code types are available to be read by the bar code reader - Code 39, Interleaved 2 of 5, Codabar, and Code 128. Certain combinations of bar code types may be enabled at any one time. Default codes are enabled for Code 39 and Code 128, neither of which can be disabled.

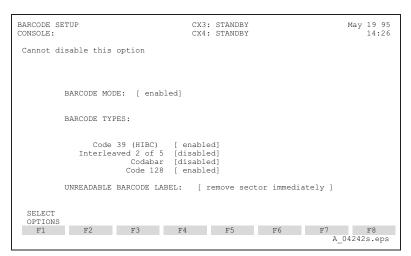
Additional options may be set for bar code types Code 39, Interleaved 2 of 5, and Codabar. These options allow the user to further define the bar code type, and are available through **F1 SELECT OPTIONS** when the particular bar code type is enabled. Refer to Appendix H for more information on barcodes.

- From the MASTER Screen, press F4 SPECIAL FUNCTION.
- 2. Cursor and **SELECT 4**. System Setup, or type **4 ENTER**.
- 3. Cursor and **SELECT 3**. Bar Code Setup, or type **3 ENTER**.

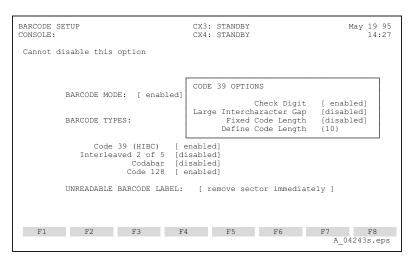


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4. Verify that the Bar Code mode is set to [enabled]. Cursor to the toggle fields for each bar code type and use SELECT to toggle each type to [enabled] or [disabled].



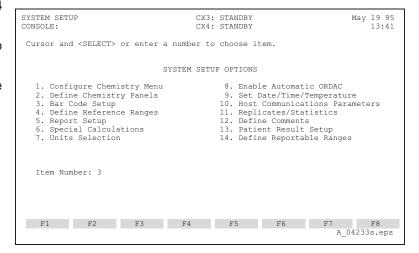
- For Code 39, Interleaved 2 of 5, or Codabar, press F1 SELECT OPTIONS to modify parameters specific to the bar code type enabled.
- 6. Use the cursor to access the parameter to be modified. Use SELECT to set the desired option in toggle fields. Input fields require a numeric entry as described in the message area of the screen. Press PREV SCREEN to close the option window.
- 7. Continue to set additional options for other bar code types as desired.
- When the desired option is set for each type, press PREV SCREEN to return to the SYSTEM SETUP Screen or press MASTER SCREEN to return to the MASTER Screen.



Unreadable Bar Code Label

This function allows the operator to select how the system will handle sectors with unreadable bar code labels. The sectors can be immediately off-loaded, or all readable bar code samples can be processed before the sector is off-loaded.

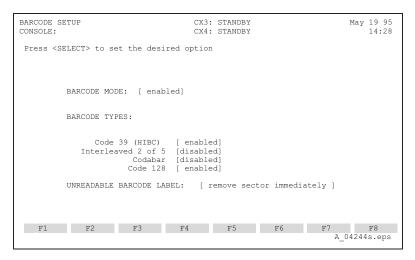
- 1. From the MASTER Screen, press **F4 SPECIAL FUNCTION**.
- 2. Cursor and **SELECT 4**. System Setup or type **4** and press **ENTER**.
- 3. Cursor and **SELECT 3**. Bar Code Setup, or type **3** and press **ENTER**.



4. Cursor to the toggle field for Unreadable Barcode Label.

Use **SELECT** to toggle between REMOVE SECTOR IMMEDIATELY (default) and PROCESS READABLE TUBES ONLY.

Press PREV SCREEN or MASTER SCREEN to exit.



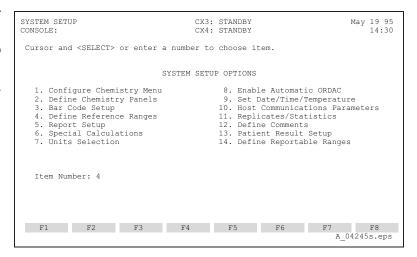
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6.5.1.4 Reference Ranges

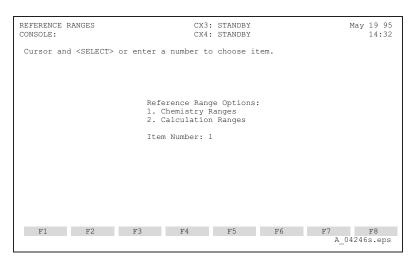
This option allows the operator to define the normal and critical ranges used in their facility, allowing differentiation for age groups as well as for gender. Up to ten age ranges may be defined per chemistry (or calculation) sex/sample type. It is recommended that each facility establish reference ranges based on its own geographical population. If desired, a default reference range for each chemistry or calculation may be designated by the operator from among the established ranges. Reference Ranges may be viewed by the operator while the system is running, but may be established or edited only when the instrument is in Standby.

Defining the Reference Ranges

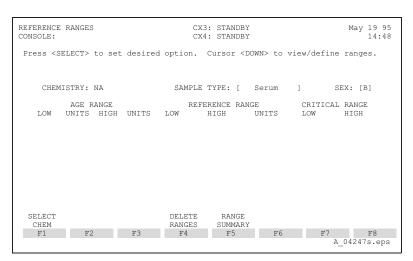
- 1. From the MASTER Screen, press **F4 SPECIAL FUNCTION**.
- Cursor and SELECT 4. System Setup or type 4 ENTER.
- 3. Cursor and **SELECT 4**. Define Reference Ranges or type **4 ENTER**.



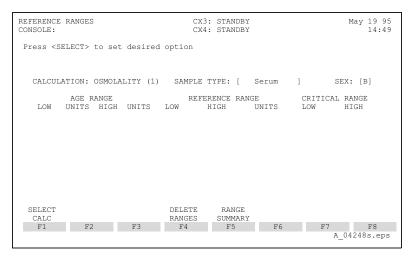
 Cursor and SELECT 1. Chemistry Ranges, or type 1, ENTER; or SELECT 2. Calculation Ranges, or type 2, ENTER.



 If Chemistry Ranges is selected, the initial reference range screen is displayed with the chemistry field set to the first configured chemistry. To display the screen for a different chemistry press F1 SELECT CHEM.



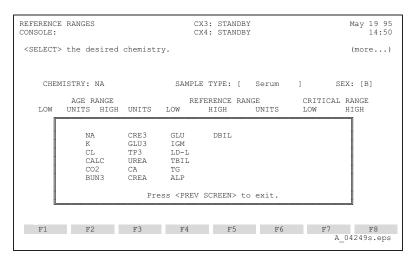
 If Calculation Ranges is selected, the initial reference range screen is displayed with the calculation field set to the first configured calculation. To display the screen for a different calculation, press F1 SELECT CALC.



7. Cursor and **SELECT** the desired chemistry or calculation. The chemistry or calculation selection window closes and the cursor is displayed at the Sample Type field.

NOTE

For DAT chemistries, cutoff values (mA/min) are printed instead of reference ranges. (Reference ranges are not applicable.) The cutoff values are printed on all report formats except the Patient Multi-Sample Report.

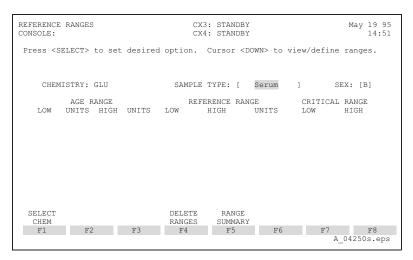


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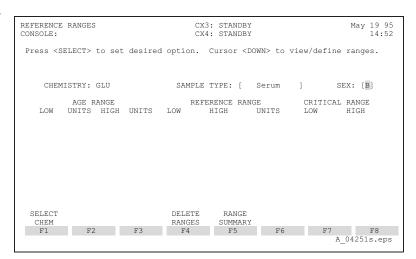
8. Press **SELECT** to set the desired sample type.

NOTE

Sample type for calculations is defined in the Special Calculations function (refer to Section 6.5.1.6). Therefore, the sample type is not accessible in this window.



9. Use **SELECT** to define the sex for reference range (Male, Female, or Both).

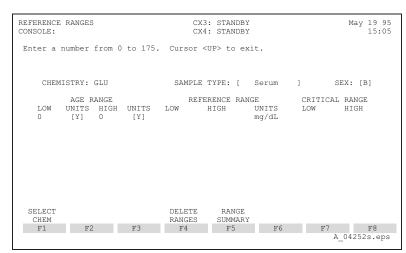


10. Use the Down arrow to move to the Low Age Range field of the first range line. Enter the Low age value.

NOTE

Maximum entries per unit of age are:

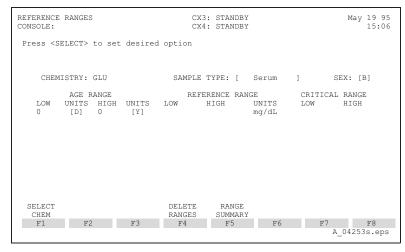
Hours-168 Days-35 Weeks-16 Months-24 Years-175



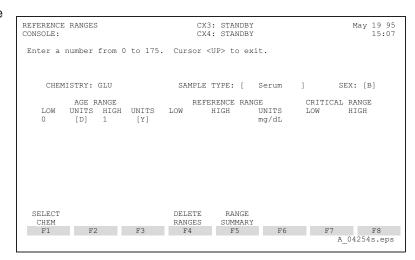
11. Press **SELECT** to set the age units (hours, days, weeks, months, years) for the Low age value. Press **ENTER**.

NOTE

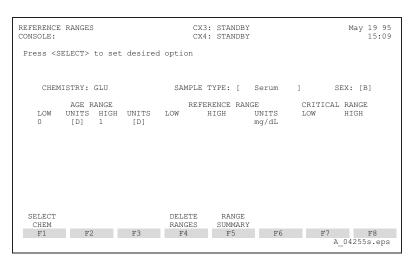
Age ranges should be consecutive, but not overlapping. Creating non-consecutive age ranges could result in a reference range not being printed.



12. Enter the High age value for the range.



13. Press **SELECT** to set the age units for the High age value.

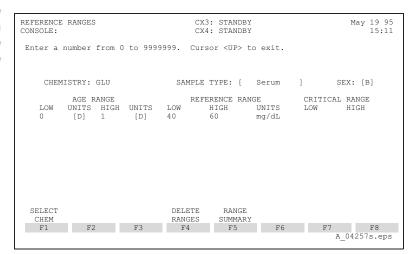


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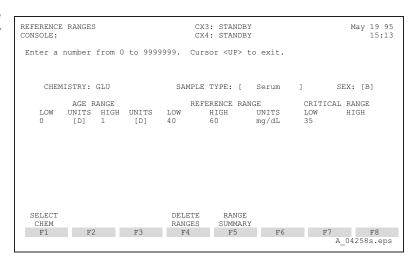
14. Enter the Low reference value.

REFERENCE RANGI CONSOLE:	ES		STANDBY STANDBY		May 19 95 15:10		
Enter a numbe:	r from 0 to 99	99999. Curso	or <up> to</up>	exit.			
CHEMISTRY	: GLU	SAMPLE T	YPE: [Serum]	SEX: [B]		
	RANGE				CRITICAL RANGE		
LOW UNITS	S HIGH UNITS 1 [D]			UNITS mg/dL	LOW HIGH		
SELECT CHEM		DELETE RANGES	RANGE SUMMARY				
0.1100.1	F2 F3	F4	F5	F6	F7 F8		
					A_04256s.eps		

15. Enter the High reference value. The units selected for the chemistry in System Setup are displayed; these values apply to both the reference and critical ranges.



 Enter a Low critical value. This value must be less than or equal to the Low reference value.



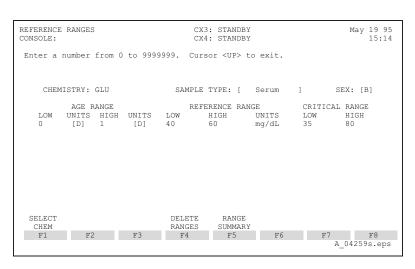
17. Enter a High critical value. This value must be greater than or equal to the High reference value. To continue entering additional ranges for this chemistry/sample type/sex, press ENTER, the Right arrow key, or the Down arrow to move to the next input line.

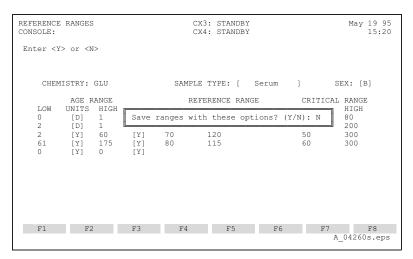
Age ranges must be consecutive and cannot overlap. When all range lines have been defined for the chemistry, cursor up to the top range line and press the Up arrow key.

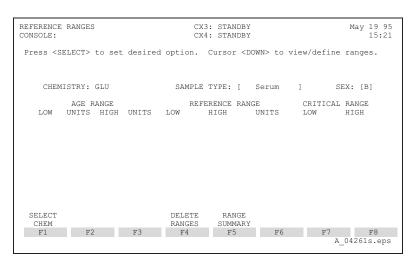
18. The operator is prompted to answer whether or not to save the range definition. To save the ranges as defined type Y, ENTER at the prompt. The cursor then moves to the Sample Type field, allowing the operator to edit Sample Type/Sex.

To continue defining Reference Ranges, proceed to Step 19. To exit Reference Ranges, press **PREV SCREEN** to return to the SYSTEM SETUP Screen or press **MASTER SCREEN** to return to the MASTER Screen.

 Press F1 SELECT CHEM. Select the same chemistry to set up the same chemistry with different Sample Type or Sex.







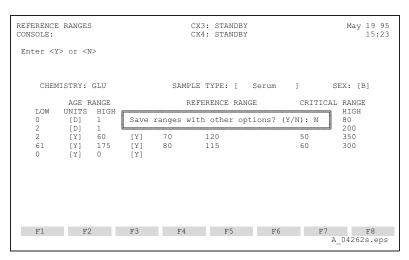
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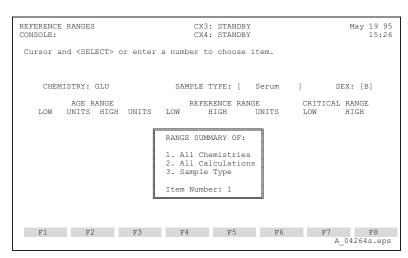
- 20. To save the ranges as defined with edits to Sample Type/Sex fields, type Y, ENTER at the prompt. If N is entered, the range lines are not saved and the cursor returns to the Sample Type field where the operator can edit the Sample Type and Sex fields again.
- 21. After both prompts have been answered, the operator may repeat steps 4 through 18 by pressing F1 SELECT CHEM to define ranges for subsequent chemistries; or F1 SELECT CALC to define ranges for subsequent calculations, if calculation ranges are being defined.
- 22. To obtain a summary, press F5 RANGE SUMMARY. Enter the Reference Range Summary to be displayed.
- 23. To obtain a hard copy of the summary displayed, press **F1 PRINT** (refer to Figure 6-9).

NOTE

When paging through the Range Summary display, note that **PAGE UP** displays the first page of the previous chemistry.

24. Press PREV SCREEN to return to the SYSTEM SETUP Screen, or press MASTER SCREEN to return to the MASTER Screen.





12 Jun 95 14:40:09 PAGE 1

RANGE SUMMARY	FOR:	Α	11 (Flu	uids					* = DEF	AULT RANG
CHEMISTRY	SEX				VGE			RANGE	UNITS		L RANGE
BUN3 Serus	В				175Y			29	mg/dL	****	> 100
GLU3 Serum	В			_	1D 23M 6ØY 175Y	ହେ ୧୭	_	90 110 115 125	mg/dL	(35 (40 (40 (40	> 150 > 300 > 400 > 400
GLU3 CSF	В		ØY		175Y	40	***	70	mg/dL	****	****
CRE3 Serum	В	*	6Y		5Y 1ØY 175Y	0.3 0.5 0.5	-		mg/dL	****	****
TP3 Serum	В	*	0Y	_	175Y	6.7	_	8.2	g/dL	****	****
TP3 CSF	В	*		-	1M 6M 175Y	30 15	_		#g/dL	****	****
ALB Serum	В				12M 175Y	2.9 3.5	_	5.5	g/dL	****	****
CHOL Serum	В		2Y		23M 19Y 175Y	45 85 100	_	119	mg/dL	****	****
PHOS Serum	B				12Y 175Y		-	6.0 4.5	mg/dL	(2.0 (1.0	****
CL Serum	В	*	ØY		175Y			110	mmo1/L	(80) 1 15
CL Random Urine	В		ØY		175Y	110	_	250	mmol/L	****	****
CL CSF	В		ØΥ	_	175Y	118	_	132	##ol/L	****	****
CO2 Serum	В	*			23M 175Y	18 21		28 31	mmol/L	<15 <15	> 45 > 50
K Serum	В	*	ØY.	_	175Y	3.5	_	5.0	mmol/L	(2.5	>6.5

Figure 6-9. Reference Ranges

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Selecting a Default Reference Range

After defining all ranges for a given chemistry, or calculation/sample type/sex combination, a default reference range may be selected. Default ranges may be selected for each such combination defined by the operator; only one range may be designated as the default range per REFERENCE RANGE Screen. The default range is used whenever an age is not entered in demographics for a given sample. If a default range is not selected and no age is entered in demographics, a reference range will not print on the report.

 From the REFERENCE RANGES Screen, position the cursor on the line which will be designated as the default range.

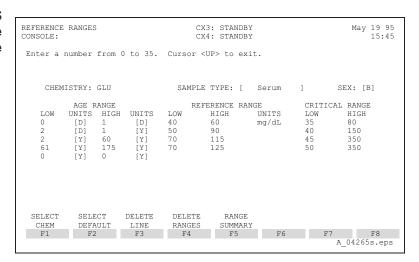
NOTE

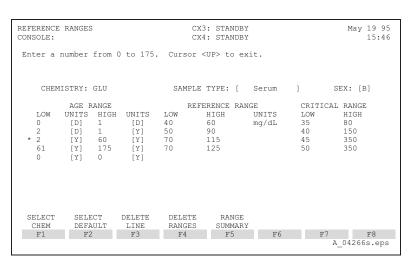
If only one range line is entered for the Reference Range, or if Critical Range values are not entered, press **ENTER** or the DOWN arrow to activate the F2 SELECT DEFAULT function key on the display.

 Press F2 SELECT DEFAULT. The default range line will be marked with an asterisk (*).

To de-select a default range, position the cursor on the designated range line and press **F2 SELECT DEFAULT**. Then follow steps 1 and 2 to assign a new default range.

3. Save the default range and normal reference ranges by using the UP arrow key to move to the top of the display. When prompted to save ranges with displayed options, type Y and press ENTER. Answer N and press ENTER to the prompt if you do not wish to save the ranges as currently displayed.





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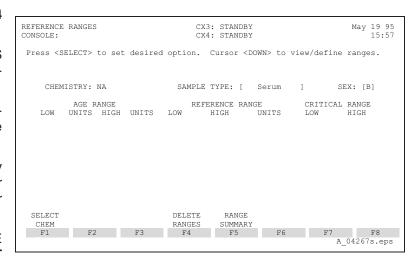
Deleting a Line from the Reference Range

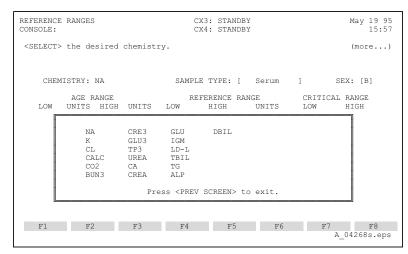
Once Reference Ranges have been established for a chemistry or calculation, the operator may delete a specified range line.

NOTE

F3 DELETE LINE is only active in REFERENCE RANGE Screens with entered values.

- 1. From the MASTER Screen, press **F4 SPECIAL FUNCTIONS**.
- From the SPECIAL FUNCTIONS Screen, cursor and SELECT 4. System Setup or type 4 ENTER.
- From the System Setup Screen, cursor and SELECT 4. Reference Ranges or type 4 ENTER.
- Cursor and SELECT 1. Chemistry Ranges, or type 1, ENTER; or SELECT 2 Calculation Ranges, or type 2, ENTER.
- From the main REFERENCE RANGES Screen, press F1 SELECT CHEM; or F1 SELECTCALC if Calculation Ranges was selected.
- A window will display all chemistries or calculations. Cursor to the chemistry (or calculation) desired and press SELECT.



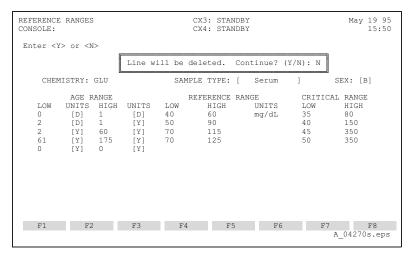


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- 7. The first Reference Range for the chemistry or calculation selected is displayed. To delete a range line for the chemistry (or calculation) sex/ sample type currently displayed, position the cursor on the line to be deleted.
- 8. Press F3 DELETE LINE.

REFERENCE RANGES CONSOLE:	CX3: STANDBY CX4: STANDBY	May 19 95 15:49		
Enter a number from 0 to	175. Cursor <up> to exit.</up>			
CHEMISTRY: GLU	SAMPLE TYPE: [Serum] SEX: [B]		
AGE RANGE	REFERENCE RANGE	CRITICAL RANGE		
LOW UNITS HIGH UNI 0 [D] 1 [D] 2 [D] 1 [Y] 2 [Y] 60 [Y] 61 [Y] 175 [Y]] 40 60 mg/dL] 50 90] 70 115] 70 125	LOW HIGH 35 80 40 150 45 350 50 350		
0 [Y] 0 [Y	1			
SELECT SELECT DELE	TE DELETE RANGE			
CHEM DEFAULT LIN				
F1 F2 F3	F4 F5 F6	F7 F8 A_04269s.eps		

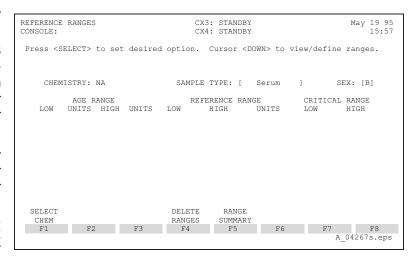
- A window displays a note that the designated line will be deleted and prompt the operator to confirm with a Y/N response. Type Y and press ENTER to confirm the deletion, or N and press ENTER to cancel the deletion request.
- 10. To delete another reference range line, repeat steps 3 through 8.
- 11. To exit press **PREV SCREEN** to return to the SPECIAL FUNCTIONS Screen, or **MASTER SCREEN** to return to the MASTER Screen.

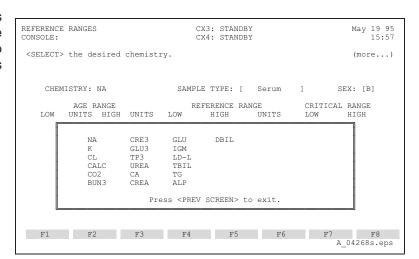


Deleting a Reference Range

An operator may delete an entire set of Reference Ranges specific to a particular chemistry (or calculation) sex/sample type combination.

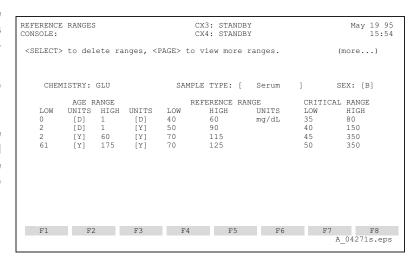
- From the MASTER Screen, press F4 SPECIAL FUNCTIONS.
- From the SPECIAL FUNCTIONS Screen, cursor and SELECT 4. System Setup or type 4, ENTER. From the SYSTEM SETUP Screen, cursor and SELECT 4. Reference Ranges or type 4, ENTER.
- Cursor and SELECT 1 Chemistry Ranges or type 1, ENTER; or SELECT 2. Calculation Ranges, or type 2, ENTER.
- 4. From the main REFERENCE RANGES Screen, press **F4 DELETE RANGES**.
- A window will display all chemistries or calculations which currently have Reference Ranges set up. Cursor to the chemistry desired and press SELECT.





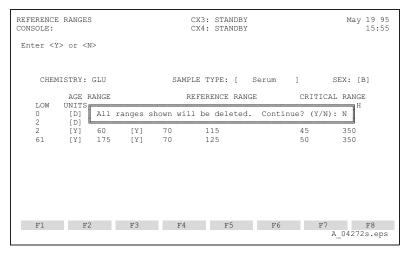
The first Reference Range for the chemistry (or calculation) selected is displayed. To delete the ranges currently displayed, press SELECT.

To view additional ranges for the chemistry (or calculation) selected, press **PAGE UP** or **PAGE DOWN**. Subsequent ranges for the same chemistry (or calculation) are deleted by pressing **SELECT** when the appropriate ranges for deletion are displayed.



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- 7. At the prompt, type **Y** and press **ENTER** to confirm the deletion, or **N** and press **ENTER** to cancel.
- To delete ranges for other chemistries (or calculations), press F4 DELETE RANGES and follow steps 3 through 6.
- To exit press PREV SCREEN to return to the SPECIAL FUNCTIONS Screen, or MASTER SCREEN to return to the MASTER Screen.



6.5.1.5 Report Setup

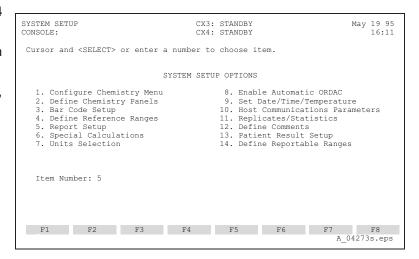
This option allows the operator to choose the format in which patient and control results are to be printed, as well as define the header which will appear at the top of each report. CAP information (CAP ID# and CAP Attention Person) may also be defined in Report Setup. Alternatively, the report can be suppressed (i.e., results are being sent to a host computer). In this case, the printer will continue to output status reports on demand; only the patient result reports are suppressed. Calibration and control reports will continue to print. The operator may also define the character pitch that patient, control and all other reports will print. These are not selectable at the printer.

NOTE

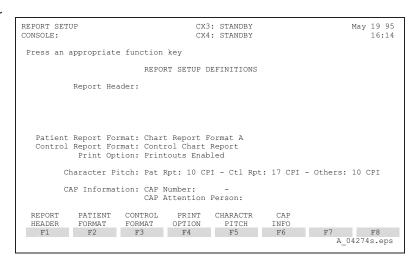
Report Setup may be viewed at any time; the system must be in Standby to edit patient report format, control report format, print character pitch or CAP information. Print Option (enable/disable) may be changed at any time.

Defining the Report Header

- From the MASTER Screen, press F4 SPECIAL FUNCTION.
- Cursor and SELECT 4. System Setup, or type 4 ENTER.
- 3. Cursor and **SELECT 5**. Report Setup, or type **5 ENTER**.

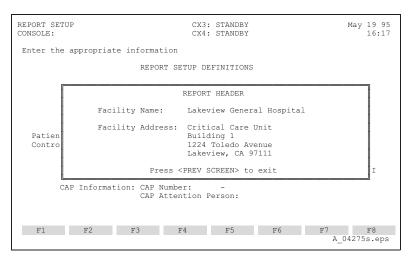


 This screen displays the default or current report parameters. Press F1 REPORT HEADER.

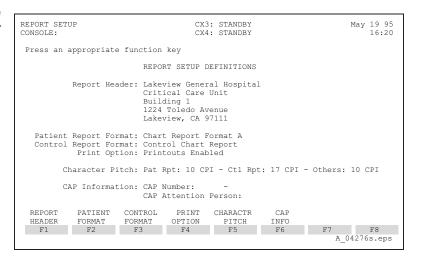


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5. Type the header text that is to appear at the top of result reports. For Facility Name, space for 30 characters is available. Press ENTER to move to facility address. The facility address provides space for 4 lines of 30 characters each.



Press PREV SCREEN to close the window and update the report header display.

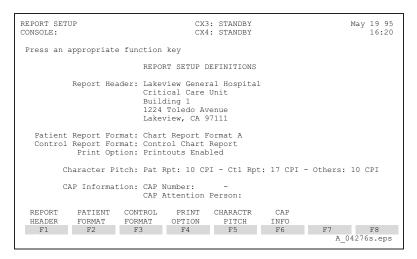


Selecting a Patient Report Format

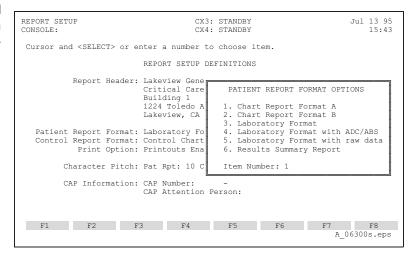
1. From the REPORT SETUP Screen, press **F2 PATIENT FORMAT**.

NOTE

Refer to Appendix E for an example of each format. Patient ID is printed only on Chart Report Formats A and B.



Cursor and SELECT the desired patient report format, or type the item number that corresponds to the format desired and press ENTER.



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Selecting a Control Report Format

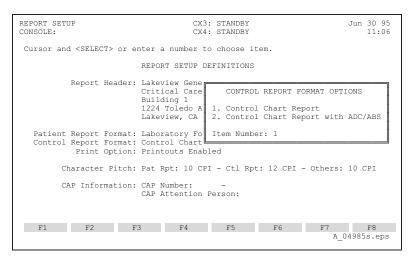
1. From the REPORT SETUP Screen, press **F3 CONTROL FORMAT**.

NOTE

Control Reports are printed whenever a sample is designated as a control during sample programming. Refer to Appendix F for an example of a control report.

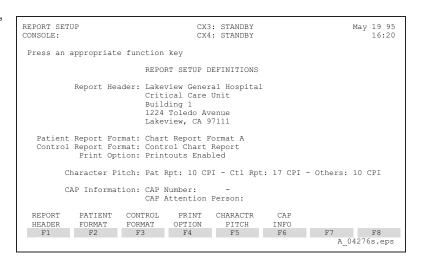
- REPORT SETUP May 19 95 CONSOLE: CX4: STANDBY 16:20 Press an appropriate function key REPORT SETUP DEFINITIONS Report Header: Lakeview General Hospital Critical Care Unit Building 1 1224 Toledo Avenue Lakeview, CA 97111 Patient Report Format: Chart Report Format A Control Report Format: Control Chart Report Print Option: Printouts Enabled Character Pitch: Pat Rpt: 10 CPI - Ctl Rpt: 17 CPI - Others: 10 CPI CAP Information: CAP Number: CAP Attention Person: CONTROL REPORT PATTENT PRINT CHARACTR CAP
 HEADER
 FORMAT
 FORMAT
 OPTION
 PITCH
 INFO

 F1
 F2
 F3
 F4
 F5
 F6
 F8 A_04276s.eps
- Cursor and SELECT the desired control report format, or type the item number that corresponds to the format desired and press ENTER.
- Press PREV SCREEN to return to the SYSTEM SETUP Screen or press MASTER SCREEN to return to the MASTER Screen.



Setting the Print Option

1. From the REPORT SETUP Screen, press **F4 PRINT OPTION**.

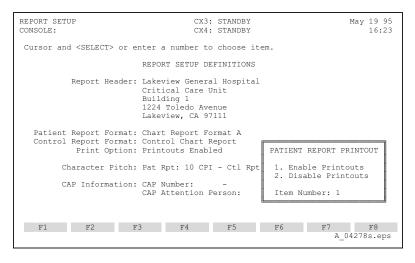


Cursor and SELECT the desired print option (Enabled or Disabled) or type the item number and press ENTER.

NOTE

The option to send/not send to Host is available through System Setup, Host Communications Parameters.

3. Press **PREV SCREEN** to return to the SYSTEM SETUP Screen, or press **MASTER SCREEN** to exit.

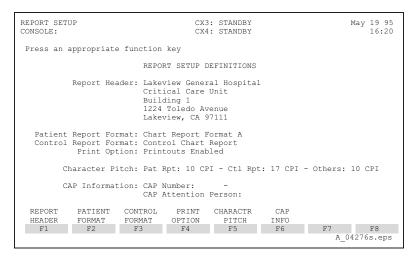


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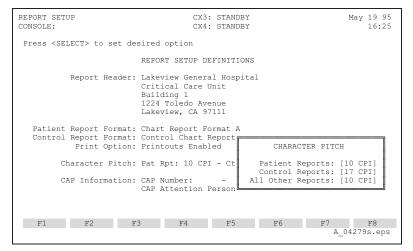
Setting the Print Character Pitch

This option allows the operator to select a character pitch of the printed reports. The full page width defaults are: Patient reports, 10 C.P.I.; Control reports, 12 C.P.I.; and All others, 10 C.P.I. For example, a patient report with 20 C.P.I. will print a 1/2 page vertical report.

1. From the REPORT SETUP Screen, press **F5 CHARACTER PITCH**.

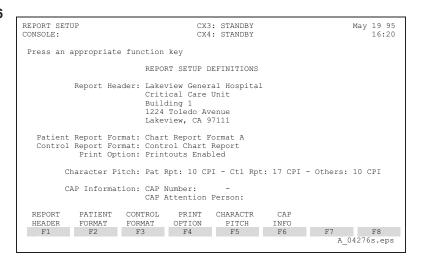


- Cursor to the desired report and press SELECT to toggle the pitch options of 10, 12, 17 and 20 C.P.I. The control report will have pitch options of 12, 17 and 20 C.P.I.
- 3. Press **PREV SCREEN** to return to the SYSTEM SETUP Screen, or press **MASTER SCREEN** to exit.

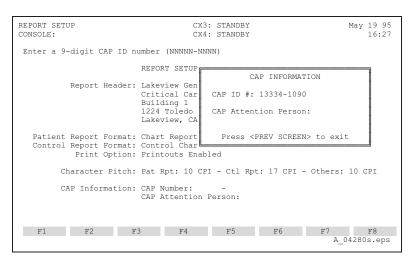


Defining CAP Information

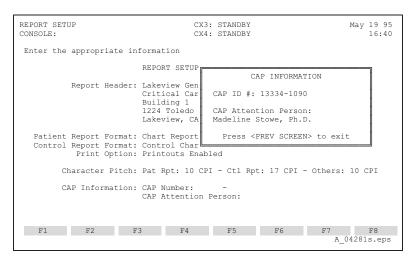
 To define CAP information, press F6 CAP INFO.



 Enter the CAP ID # (must be 9 digits) in the format displayed, using the cursor keys to move between the first and second halves of the CAP ID field. When the entry is complete, press ENTER.



- Enter the CAP Attention Person (up to 30 characters). Press PREV SCREEN to close the window and update the display.
- Press PREV SCREEN to return to the SYSTEM SETUP Screen, or press MASTER SCREEN to return to the MASTER Screen.



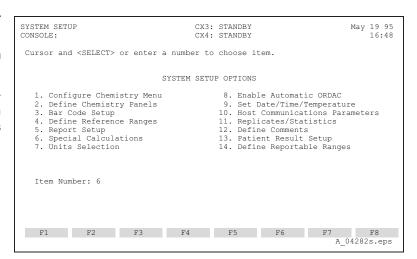
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6.5.1.6 Special Calculations

This option provides the user with a means of selecting predefined calculations that are to be reported with each sample. The system provides availability of 40 calculations; thirteen are pre-programmed and cannot be modified or deleted from the system (with the exception of Free Thyroxine Index). Twenty seven additional calculations may be defined/modified by the operator. The selected calculations are reported only if the appropriate chemistries for the equation are programmed and run for a given sample ID. While the calculations may be viewed at any time, the system must be in Standby to program or modify special calculations.

Selecting and Reviewing Pre-Programmed Calculations

- From the MASTER Screen, press F4 SPECIAL FUNCTION.
- Cursor and SELECT 4. System Setup, or type 4 ENTER.
- Cursor and SELECT 6. Special Calculations, or type 6 ENTER. The main SPECIAL CALCULATIONS Screen is displayed.



NOTE

Several pre-programmed calculations use chemistries that can be run on either the CX3 or CX4 side of the instrument. When these calculations are enabled, the operator is prompted to indicate whether CX3 or CX4 chemistries should be used to perform the calculation. When a new version of software is loaded, or if software is reloaded, the special caluclations are returned to a default of using CX4 chemistries. Operators should make sure their system is set up as desired by performing the following steps:

STEP	ACTION
1	In the Special Calculations Screen, check to see that all desired calculations are toggled to ON.
2	Cursor to the first pre-programmed calculation that is ON.
3	Toggle the calculation OFF, then back ON.
4	If appropriate, a window will prompt the operator to select CX3 or CX4 chemistries to be used for the calculation. Make the selection.
5	Repeat steps 2-4 for each of the pre-programmed calculations.

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4. Move cursor to the desired equation and press SELECT to toggle to either ON or OFF. If the equation contains chemistries which are resident on both the CX3 and CX4, a window prompts the operator to specify the instrument to be used. In those cases, either all CX3 chemistries or all CX4 chemistries will be used to calculate the result.

NOTE

CREATININE CLEARANCE (1 & 2) use creatinine values from the instrument in the following order: CRE3, CREA, and then CR-T. The operator will not be prompted to select CX4 or CX3.

SPECIAL CALCULATIONS CONSOLE:			CX3: STANDBY CX4: STANDBY			May 19 95 16:50		
Press <select> to turn</select>	calculations	ON/OI	?F			(more)		
NAME	ON/OFF		NAMI	€		ON/OFF		
5. A/G RATIO	[ON] [ON] [OFF] [OFF] [ON] [OFF] [ON] [OFF]		12.	CREA CLEAR CREA CLEAR FREE THYROX	(2)			
EDIT CALC FA	CONV CTORS F3 F4		F5	F6	F7	F8 A_04283s.eps		

NOTE

Osmolality (1 and 2), Anion Gap (1 and 2), BUN/CREA and UREA/CREA, BUN/CR-T and UREA/CR-T, and CREA CLEAR (1 and 2) are mutually exclusive---only one equation in each pair may be toggled [ON] at any one time. Both equations of a pair may be toggled [OFF] at the same time. Therefore, whenever one of the calculations in the mutually exclusive pair is toggled [ON], the other calculations will automatically be toggled [OFF].

The system checks for compatible units among chemistries in equations 1–13 only. If incompatible units are found the calculation is not performed and an error message is printed on the report

NOTE

When µmol/L is the unit selected for either CREA, CRE3, or CR-T and Timed Urine or Randome Urine is the sample type, the serum result is expressed in µmol/L while the urine result is expressed in mmol/L. This complies with the international convention for reporting urine creatinine clearance.

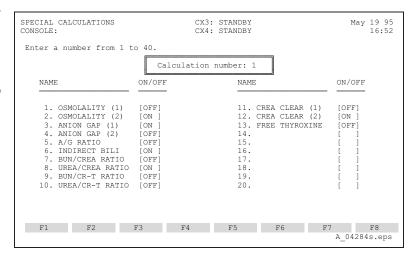
NOTE

When creatinine is selected for a Timed Urine sample, a Creatinine Clearance is automatically calculated if the Creatinine Clearance Special Calculation is enabled and the essential sample parameter information is input by the operator. The intended use of the triggered creatinine (CR-T) is to eliminate interference on serum samples. If CR-T is the only creatinine selected for a Timed Urine sample, operators are advised of the following:

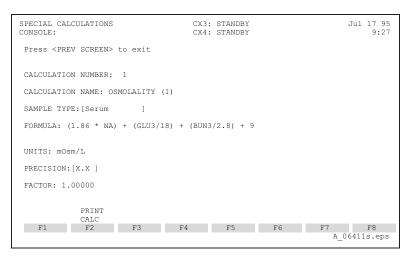
- The serum CR-T value entered in the urine parameter window of the sample program will not appear on the printed report.
- Press PRINT SCREEN after entering the urine parameters to make a permanent record of the urine parameters window for the sample program.

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- 5. Refer to Paragraph 6.5.1.6.1 for setting up Enzyme Conversion Factors.
- To view calculations 1-13, press F1 DEFINE/EDIT.
- 7. Enter the number corresponding to the calculation to be reviewed.



- 8. The calculation definition is displayed on the SPECIAL CALCULATIONS Screen.
- Press PREV SCREEN to return to the main SPECIAL CALCULATIONS Screen, or press MASTER SCREEN to exit.



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Table 6-14. Special Calculation Formulas

CALCULATION	FORMULA
OSMOLALITY(1)	(1.86 * NA) + (GLU/18) + (BUN/2.8) + 9
OSMOLALITY(2)	(1.86 * NA) + (GLU/18) + (UREA) + 9
ANION GAP (1)	NA - (CL + CO2)
ANION GAP (2)	(NA + K) - (CL + CO2)
A/G RATIO	ALB/(TP - ALB)
INDIRECT BILI	TBIL - DBIL
BUN/CREA RATIO	BUN/CREA
UREA/CREA RATIO	UREA/(CREA * .0884)
FREE THYROXINE INDEX	T4 X (TU%/34.2)
BUN/CR-T RATIO	BUN/CR-T
UREA/CR-T RATIO	UREA/(CR-T * .0884)
CREATININE CLEARANCE (1)	$[(u \star v)/p] \star (1.73/A)$ uses mLs/min
CREATININE CLEARANCE (2)	[(u * v)/p] * (1.73/A) uses mLs/sec
CHEMISTRY	DEFAULT UNITS*
NA	mmol/L
К	mmol/L
CL	mmol/L
CO ₂	mmol/L
GLU/GLU3	mg/dL
BUN/BUN3	mg/dL
TBIL	
T DIE	mg/dL
ALB	g/dL
	_
ALB	g/dL
ALB TP/TP3	g/dL g/dL

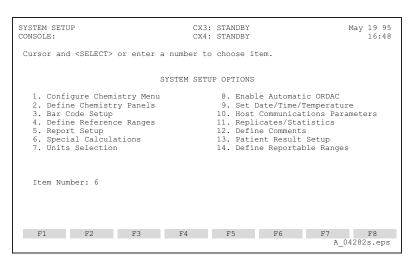
The CX4/CX7 calculates and reports the pre-programmed calculations in default units (refer to Table 6-14), regardless of the units selected by the operator in System Setup. The only exceptions are UREA/CREA, URE3/CRE3, or UREA/CR-T which use operator-selected units.

To report calculated values which reflect units other than default units, the operator must create and enable a Custom Calculation. The system applies conversion factors to the custom calculations to account for differences between default units and alternative operator-selected units.

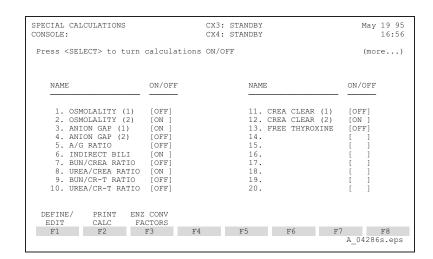
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Defining Custom Calculations

- From the MASTER Screen, press F4 SPECIAL FUNCTION.
- Cursor and SELECT 4. System Setup or type 4 ENTER.
- Cursor and SELECT 6. Special Calculations or type 6 ENTER. The main SPECIAL CALCULATIONS Screen is displayed.



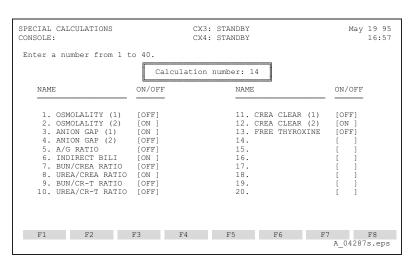
4. Press F1 DEFINE/EDIT.



5. Enter a calculation number that is currently undefined.

NOTE

Ordinary timed urine calculations (e.g. Urine NA, Urine CA) are automatically performed and reported along with the aliquot result. The operator must program the sample as a Timed Urine and enter appropriate sample information in order for the calculation to be performed. For a more detailed description of Creatinine Clearance, refer to Appendix G.

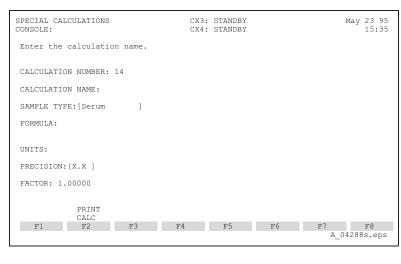


6. A blank define/review screen is displayed. The minimum required entries to save a custom calculation definition are calculation number, name, sample type, and formula. Enter the calculation name (up to 15 characters) and press ENTER.

NOTE

Each custom calculation name must be unique, and may not be the same as a pre-programmed calculation, a Beckman chemistry name, or a defined UDR.

Press SELECT to toggle the appropriate sample type (default is serum).
 Only one sample type may be defined for a calculation.



```
SPECIAL CALCULATIONS

CX3: STANDBY

CONSOLE:

CX4: STANDBY

Enter the calculation name.

CALCULATION NUMBER: 14

CALCULATION NAME: CKMB%

SAMPLE TYPE:[Serum ]

FORMULA:

UNITS:

PRECISION:[X.X]

FACTOR: 1.00000

PRINT
CALC

F1 F2 F3 F4 F5 F6 F7 F8

A_04289s.eps
```

Enter the calculation formula. The formula should not include the calculation name (see example below for Osmolality formula).

```
SPECIAL CALCULATIONS
                                CX3: STANDBY
                                                             May 19 95
                                CX4: STANDBY
Enter the calculation formula.
CALCULATION NUMBER: 14
CALCULATION NAME: CKMB%
SAMPLE TYPE: [Serum
FORMULA: CKMB/CK*100
UNITS:
PRECISION: [X.X ]
FACTOR: 1.00000
           PRINT
                                                          F8
A_04290s.eps
F1 F2
                  F3 F4 F5 F6 F7
```

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Field Length: 64 alpha numeric characters, including spaces

Chemistries: Maximum of six chemistries per formula. Must use approved abbreviation for

chemistry name, or in the case of UDRs must use the abbreviation selected in UDR Setup. All chemistries in formula must be configured on the system.

Precedence of Symbols: ()

** to denote exponent (1-99 allowed)

* to denote multiply or / to denote divide

+ or -

. (a period) to express a percentage as a decimal (numbers less than 1.0 must use a zero before the decimal point, e.g., 0.9)

EXAMPLE OF FORMULA FOR OSMOLALITY: (1.86 * NA) + (GLU/18) + (BUN/2.8) + 9

 Enter calculation units if desired (not a required entry - default is no units).
 Units are applied to the final calculation result only.

IMPORTANT NOTE

Operators are responsible for unit compatibility within all custom calculations. Calculations are based on operator selected units. The system does not check for unit compatibility in custom calculations 14-40, and no error message is displayed if calculations are performed on chemistries with incompatible units.

- Specify the precision of the calculated result if desired using SELECT. Available selections are x, x.x and x.xx with a default selection of x.x.
- 11. The operator may define a factor for use in correlating to other systems. Enter a factor from 0.00001 to 99999999. The default is 1.00000.

```
SPECIAL CALCULATIONS CX3: STANDBY May 19 95
CONSOLE: CX4: STANDBY 17:02

Enter the desired units.

CALCULATION NUMBER: 14

CALCULATION NAME: CKMB%

SAMPLE TYPE:[Serum ]

FORMULA: CKMB/CK*100

UNITS: %

PRECISION:[X.X ]

FACTOR: 1.00000

PRINT
CALC

F1 F2 F3 F4 F5 F6 F7 F8
A_04291s.eps
```

```
SPECIAL CALCULATIONS CX3: STANDBY May 19 95
CONSOLE: CX4: STANDBY 17:03

Press <SELECT> to set desired option

CALCULATION NUMBER: 14

CALCULATION NAME: CKMB%

SAMPLE TYPE:[Serum ]

FORMULA: CKMB/CK*100

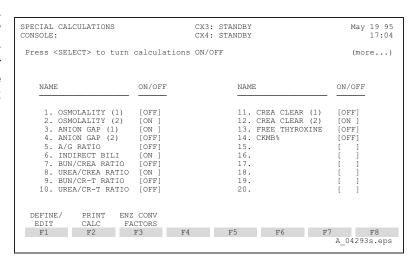
UNITS: %

PRECISION:[X.X]

FACTOR: 1.00000

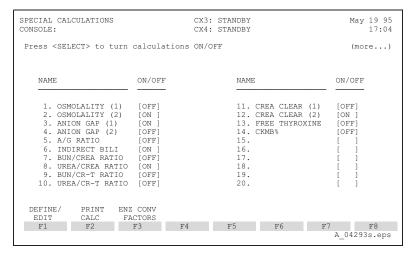
PRINT
CALC
F1 F2 F3 F4 F5 F6 F7 F8
A_04292s.eps
```

12. Press PREV SCREEN to save information, exit the DEFINE/REVIEW Screen and return to the main SPECIAL CALCULATION Screen, or press MASTER SCREEN to save the definition and return to the MASTER Screen.

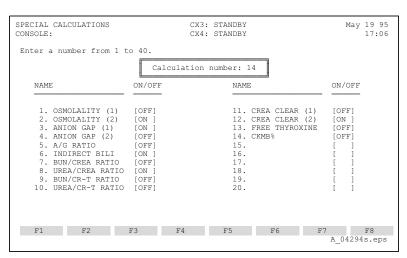


Editing a Custom Calculation

- From the MASTER Screen, press F4 SPECIAL FUNCTION.
- 2. Cursor and **SELECT 4**. System Setup, or type **4 ENTER**.
- Cursor and SELECT 6. Special Calculations, or type 6 ENTER.
- 4. Press F1 DEFINE/EDIT.

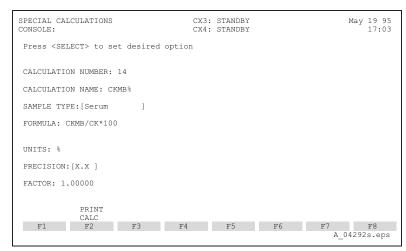


5. Enter a calculation number (14-40) that is currently defined.



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- The SPECIAL CALCULATIONS Screen is displayed with the currently programmed information.
- Move the cursor to the appropriate field and make edits as appropriate.
 To save changes and exit the display, press PREV SCREEN or MASTER SCREEN.



Printing a List of Special Calculations

- From the MASTER Screen, press F4 SPECIAL FUNCTION.
- Cursor and SELECT 4. System Setup, or type 4 ENTER.
- Cursor and SELECT 6. Special Calculations, or type 6 ENTER. The main Calculations Screen is displayed.
- Press F2 PRINT CALC. All currently defined calculations will be printed.

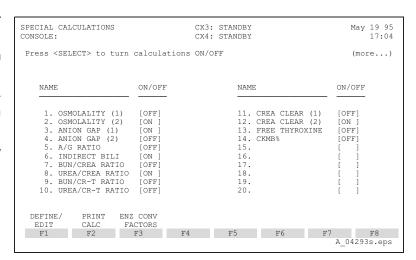
NOTE

In the Define/Review display, the operator may print a copy of the currently displayed information by pressing **F2 PRINT CALC**.

Clearing a Custom Calculation

Only custom calculations and the FTI calculation may be cleared from the system.

- From the MASTER Screen, press F4 SPECIAL FUNCTION.
- Cursor and SELECT 4. System Setup, or type 4 ENTER.
- Cursor and SELECT 6. Special Calculations, or type 6 ENTER. The main Calculations Screen is displayed.
- Move the cursor to the custom calculation to be cleared (the cursor will rest in the ON/OFF area).
- Press CLEAR. The calculation and associated definition will be cleared from the screen.



6.5.1.6.1 Enzyme Conversion Factors

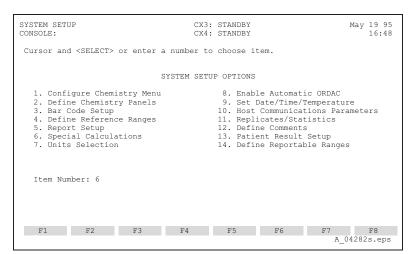
This option allows the user to report enzyme results at a temperature different than that used for the actual analysis. The SYNCHRON CX System can operate at either 30°C or 37°C, however, the results for enzymes may be reported to reflect 25°C, 30°C, or 37°C. Changes to enzyme conversion factors can be made only when the system is in Standby.

NOTE

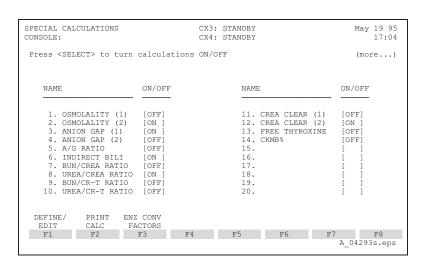
25°C factors are established by Beckman Instruments Incorporated, and are specific to Beckman SYNCHRON Reagents used on the SYNCHRON CX analyzers.

Selecting Enzyme Conversion Factors

- From the MASTER Screen, press F4 SPECIAL FUNCTIONS.
- Cursor and SELECT 4. System Setup, or type 4 ENTER.
- 3. Cursor and **SELECT 6**. Special Calculations, or type **6 ENTER**.

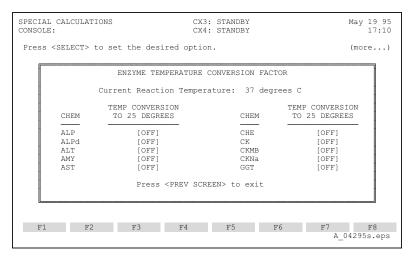


4. Press F3 ENZ CONV FACTORS.



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- Move cursor to the desired enzyme and press SELECT to enable the temperature conversion factor for 25°C (ON). Pressing SELECT again toggles to disable the factor (OFF).
- Press PREV SCREEN to close window.
- 7. Press **PREV SCREEN** to return to the SYSTEM SETUP Screen or press **MASTER SCREEN** to exit.

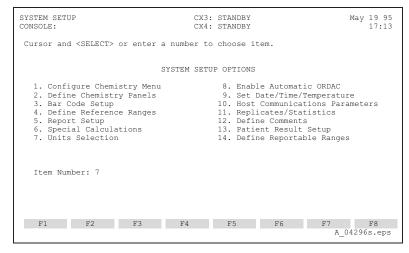


6.5.1.7 Unit Selection

This option provides the operator with a means of selecting the units and the decimal precision to which the results are reported. If the units are altered, all features affected by the change, such as reference ranges and calibration values, will be automatically converted to match the new units. Units cannot be changed for chemistries which are defined for a control in QC. User-defined chemistries are not displayed from this function. Changing units for user-defined chemistries is to be done via the USER DEFINED SETUP Screen (refer to Paragraphs 8.2 and 8.3). Unit Selection can be viewed at any time, but may only be modified when the system is in Standby.

Selecting Chemistry Units

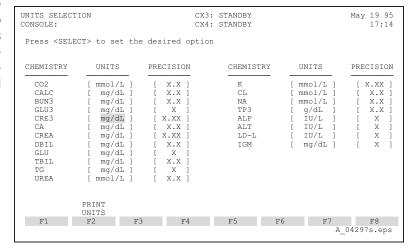
- From the MASTER Screen, press F4 SPECIAL FUNCTIONS.
- Cursor and SELECT 4. System Setup, or type 4 ENTER.
- Cursor and SELECT 7. Units Selection, or type 7 ENTER.



4. The cursor is positioned under the UNITS column; move the cursor to the chemistry of choice. Press SELECT to toggle through the allowable units until the desired unit is displayed. Use PAGE UP/PAGE DOWN to view additional lines of information.

NOTE

All chemistries are assigned default units. (Refer to Appendix D for a list of the default units.)



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- 5. All units have a corresponding recommended decimal precision for reporting results. To alter, position the cursor under the PRECISION column at the chemistry of choice. Press SELECT to toggle through the choices until the desired option is displayed. Options are X, X.X, and X.XX.
- 6. Repeat Steps 4 and 5 until all desired units have been selected.
- 7. Press **F2 PRINT UNITS** to obtain a hard-copy summary (refer to Figure 6-10).
- 8. Press **PREV SCREEN** to return to the SYSTEM SETUP Screen or press **MASTER SCREEN** to exit.

UNITS SELECT	!ION					TANDBY					Ма	y 19 17:	
Press <sele< td=""><td>CT> to se</td><td>t the</td><td>des</td><td>sired optio</td><td>on</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></sele<>	CT> to se	t the	des	sired optio	on								
CHEMISTRY	UNITS		PRE	ECISION		CHEMIST	RY		UNITS		PR	ECISI	ON
CO2	[mmol/	— L 1		X.X]		K	_	_	mmol/L	_ 1		X.XX	1
CALC	[mg/d	ьj		x.x]		CL		ĺ	mmol/L	í		X.X	
BUN3	[mg/d	L j		X.X]		NA		Ī	mmol/L	i	Ī	X.X	i
GLU3	[mg/d		Ī	X]		TP3		Ī	g/dL	ī	Ī	X.X	1
CRE3	[mg/d		Ī	X.XX		ALP		Ī	IU/L	j	Ī	X	j
CA	[mg/d	L]	[X.X]		ALT		[IU/L]	[X]
CREA	[mg/d	L]	[X.XX]		LD-L		[IU/L]	[X]
DBIL	[mg/d	L]	[X.X]		IGM		[mg/dL]	[X]
GLU	[mg/d	L]	[X]									
TBIL	[mg/d	L]	[X.X]									
TG	[mg/d	L]	[X]									
UREA	[mmol/	L]	[x.x]									
	PRINT UNITS												
F1	F2	F3		F4		F5	F6		F	7		F8	
											A 042	98s.e	ps

NOTE

When μ mol/L is the unit selected for either CREA, CRE3, or CR-T and Timed Urine or Random Urine is the sample type, the serum result is expressed in μ mol/L while the urine result is expressed in mmol/L. This complies with the international convention for reporting urine creatinine clearance.

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19 May 95 17:17:13 PAGE 1

CX7 DELTA UNITS SELECTED

CHEMISTRY	UNITS	PRECISION	
CO2 CALC BUN3 GLU3 CRE3 CA CREA DBIL GLU TBIL TG UREA K CL NA TP3 ALP ALT LD-L IGM	mmol/L mg/dL lu/L lu/L lu/L lu/L	X. X X. X X. X X. X X. X X. X X. X X. X	
			A_05083C.EPS

Figure 6-10. Units Selected

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6.5.1.8 Automatic ORDAC

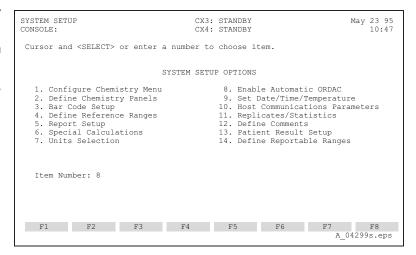
This option allows the operator to enable or disable the Automatic Overrange Detection and Correction (ORDAC) function for specified chemistries (listed below). Chemistries which are Auto ORDAC enabled are automatically diluted and repeated by the instrument if the results exceed the usable range. (The manual ORDAC function in Sample Programming is used for samples which are known to exceed the usable range. Chemistries designated with Manual ORDAC at the time of programming are diluted prior to their being run.) The Automatic ORDAC screen may be viewed at any time, but modifications are allowed only when the system is in Standby.

The ORDAC function is available for the following chemistries only:

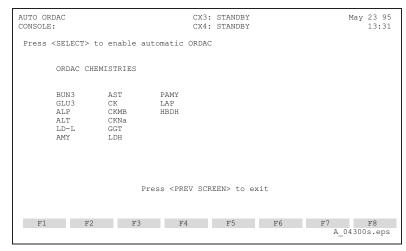
ALPd, ALP, AMY, AST, AST-, ALT, ALT-, BUN3, CK, CK-, CKMB, CKNa, CKMB, GGT, GLU3, GOT, GPT, HBDH, LAP, LD-L, LD-P, LDH, PAMY, URE3

Enabling Automatic ORDAC

- From the MASTER Screen, press F4 SPECIAL FUNCTION.
- Cursor and SELECT 4. System Setup, or type 4 ENTER.
- 3. Cursor and **SELECT 8**. Enable Automatic ORDAC, or type **8 ENTER**.



- Move cursor to the chemistry or chemistries of choice and press SELECT to enable automatic ORDAC (highlighted) or disable automatic ORDAC.
- Press PREV SCREEN to return to the SYSTEM SETUP Screen, or press MASTER SCREEN to exit.



6.5.1.9 Date/Time/Temperature

The first time the instrument is powered up, the user must set the time, date, and temperature from the DATE/TIME/TEMPERATURE Screen. Once set, changes to accommodate incidents such as converting to daylight-savings time are performed through this option. The DATE/TIME/TEMPERATURE Screen may be viewed at any time, but may only be modified when the system is in Standby.

Setting the Date, Time or Temperature

NOTE

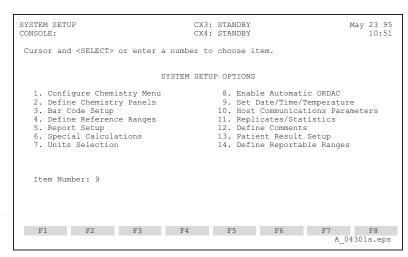
Random changes to date and time may disrupt software files. Changes to date and time should be made only at installation or for Daylight Savings changes.

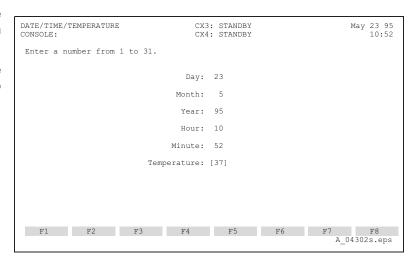
- 1. From the MASTER Screen, press **F4 SPECIAL FUNCTION**.
- 2. Cursor and **SELECT 4**. System Setup, or type **4 ENTER**.
- Cursor and SELECT 9. Set Date/ Time/Temperature, or type 9 ENTER.

NOTE

Changes to system date and/ or time may affect reagent expiration date, calibration, quality control data, within-lot calibration status and on-board stability dates for reagents.

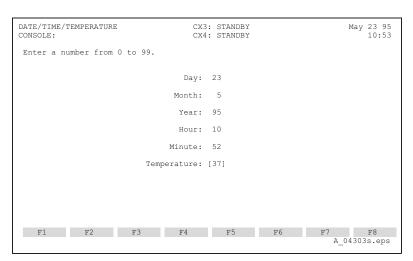
- Enter the day (1 through 31). The DATE/TIME/TEMPERATURE Screen is displayed.
- 5. Enter the month (1 through 12). The numerical entry will be converted to alpha characters for screen display.





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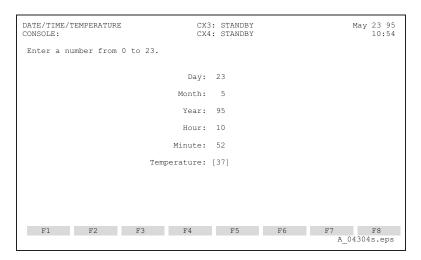
6. Enter the last two digits of the year (0-99).



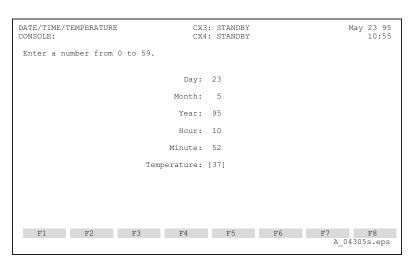
7. Enter the hours (24-hour clock).

NOTE

The time between midnight and 1 AM is 00:00 to 00:59.



8. Enter the minutes (0-59).

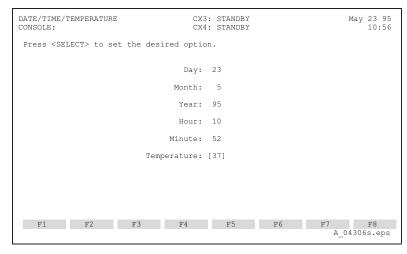


9. Press **SELECT** until the desired temperature is displayed. The system must be in standby at this time.

NOTE

The instrument can be run at 30°C or 37°C. The default temperature at installation is 37°C; the system will retain the selected temperature upon reboot. It takes approximately 30 minutes to stabilize the temperature when changed. Changing temperature will result in loss of all calibration data and within-lot calibration data upon exiting the screen.

10. When done, press PREV SCREEN to return to the SYSTEM SETUP Screen, or press MASTER SCREEN to return to the MASTER Screen. At this time the date entered is verified. If an invalid date was entered (e.g. Feb 31), the message "invalid date" is displayed and the date/time/temp screen is not exited.



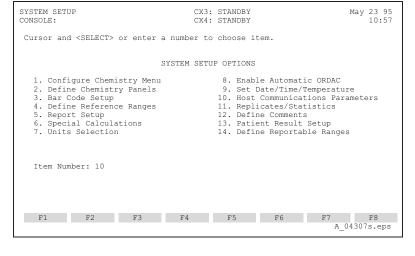
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6.5.1.10 Host Communications Parameters

This feature allows the operator to establish compatibility between the instrument and a host computer for data transmission. Host Communications Parameters may be viewed at any time, but modifications can be made only when the system is in Standby. If enabled, the system will reestablish Host Communications following Backup, Resume, Rebuild Databases, Chemistry Update and switching between sector and barcode mode. However, the operator must toggle Host Communications to the desired mode following the Restore function.

Defining Host Communications Parameters

- From the MASTER Screen, press F4 SPECIAL FUNCTION.
- Cursor and SELECT 4. System Setup, or type 4 ENTER.
- Cursor and SELECT 10. Host Communications Parameters, or type 10 ENTER.

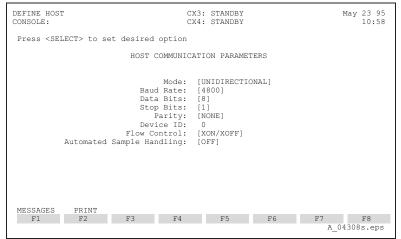


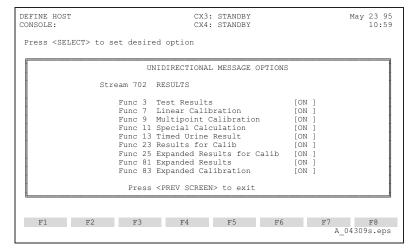
4. Refer to SYNCHRON CX4/CX5/CX7 Systems Host Computer Interface Specifications (Section Ten) and also to Table 6-15 for comprehensive documentation of the host parameters. Move cursor to the desired parameter and press SELECT to scroll through available options or enter the appropriate values.

NOTE

Automated sample handling is for use with Optional Robotics interface.

- Press F1 MESSAGES to review/edit Unidirectional or Bidirectional message options. Use PAGE UP/PAGE DOWN to access additional message options.
- Press PREV SCREEN to return to the SYSTEM SETUP Screen, or press MASTER SCREEN to exit.





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FIELD	AVAILABLE OPTIONS
MODE:	UNIDIRECTIONAL, BIDIRECTIONAL, OFF
BAUD RATE:	600, 1200, 2400, 4800, 9600
DATA BITS:	7, 8
STOP BITS:	1, 2
PARITY:	NONE, ODD, EVEN
DEVICE ID:	0 - 99
FLOW CONTROL:	XON/XOFF, RTS/CTS, NONE
AUTOMATED SAMPLE:	ON, OFF
STATUS	MESSAGES: (U)nidirectional, (B)idirectional
Stream 700/Func 2:	Host Setup ON, OFF (U,B)
Stream 701/Func 6:	Host Query ON, OFF (B)
	Auto Clear Queue ON, OFF (B)
Stream 702/Func 3:	Test Results ON, OFF (U,B)
Stream 702/Func 7:	Linear Calibration ON, OFF (U,B)
Stream 702/Func 9:	Multipoint Calibration ON, OFF (U,B)
Stream 702/Func 11:	Special Calculations ON, OFF (U,B)
Stream 702/Func 13:	Timed Urine Result ON, OFF (U,B)
Stream 702/Func 23:	Calibration Results ON, OFF (U,B)
Stream 702/Func 25:	Expanded Calib Result ON, OFF (U,B)
Stream 702/Func 81:	Expanded Results ON, OFF (U,B)
Stream 702/Func 83:	Expanded Calibration ON, OFF (U,B)
Stream 703/Func 1:	Power Up ON, OFF (U,B)
Stream 703/Func 5:	Instrument Exception ON, OFF (U,B)
Stream 703/Func 7:	Chem Change ON, OFF (U,B)
Stream 703/Func 13:	Range Change ON, OFF (U,B)
Stream 703/Func 17:	End of Run ON, OFF (U,B)
	IMPORTANT NOTE

Regarding Stream 702, Functions 3 and 81 - at least one of these functions must be set ON. Both can be ON, but both cannot be set to OFF at the same time.

*Refer to Section Ten for details

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6.5.1.11 Replicate Assays/Statistics

6.5.1.11.1 Replicate Assays

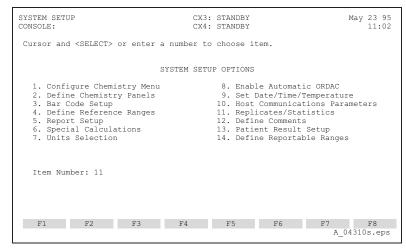
This option provides the ability to assay all samples within a run for one, two or three replicates. All results are printed and maintained in memory for recall. The Replicates/Statistics option may be viewed at any time; modifications to replicates and/or statistics can only be made when the system is in Standby.

NOTE

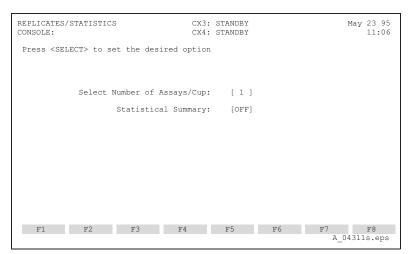
System defaults to 1 replicate following any reboot procedure. The number of replicates per sample is the number selected at the time a sector is loaded.

Setting Replicate Assays per Sample

- 1. From the MASTER Screen, press **F4 SPECIAL FUNCTION**.
- 2. Cursor and **SELECT 4**. System Setup, or type **4 ENTER**.
- Cursor and SELECT 11. Replicates/ Statistics, or type 11 ENTER.



- 4. Press **SELECT** to toggle to 1 (single replicate per sample), 2 (sample is run in duplicate), or 3 (sample is run in triplicate).
- 5. Refer to Paragraph 6.5.1.11.2 to turn on statistics.
- 6. Press **PREV SCREEN** to return to the SYSTEM SETUP Screen, or press **MASTER SCREEN** to exit.



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6.5.1.11.2 Statistics (Sector/Cup Mode only)

When enabled, this option provides the operator with a chemistry-by-chemistry statistical summary of all the results within a given sector. This can be of value in assessing the performance of the system, or as an aid in establishing population variances. This option is available only in Sector/Cup mode. Statistics option can be reviewed at any time, but may only be enabled/disabled when the system is in Standby.

NOTE

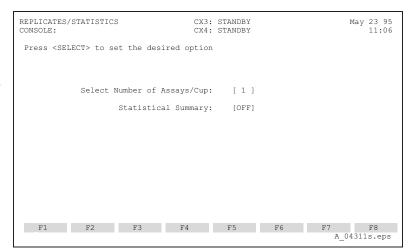
System defaults to OFF following any reboot procedure. If one or more cups in a sector are rerun, the sector statistics are recalculated to include the new results.

NOTE

When running statistical summary and/or expanded statistical summary, all results of a given chemistry are analyzed in the same units on a given sector. The units are based on the first time the chemistry is run in the sector. An example is Total Protein (cup chemistry) which can be run on serum and spinal fluids. The units are g/dL and mg/dL respectively. If a serum sample is run first then all samples, including CSF, will be analyzed in g/dL on the statistical summary report. This only occurs on the statistical summary report. This **does not** affect summary, chart and lab reports.

Enabling Statistical Summary of Results

- From the MASTER Screen, press F4 SPECIAL FUNCTION.
- 2. Cursor and **SELECT 4.** System Setup, or type **4 ENTER**.
- Cursor and SELECT 11. Replicates/ Statistics, or type 11 ENTER.

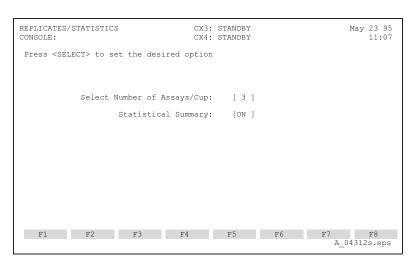


Move cursor to Statistical Summary and press SELECT to toggle to ON.

NOTE

Statistics include mean, standard deviation, and coefficient of variation.

- 5. Refer to Paragraph 6.5.1.11.1 for procedure on replicate assays.
- Press PREV SCREEN to return to the SYSTEM SETUP Screen, or press MASTER SCREEN to return to the MASTER Screen.

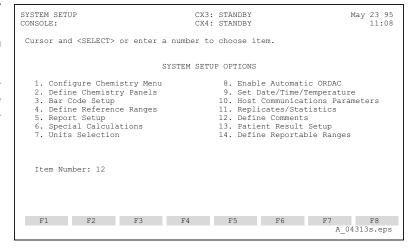


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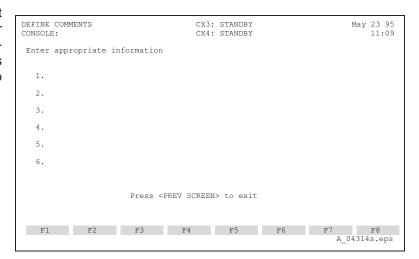
6.5.1.12 Define Comments

This option allows users to define up to 6 pre-programmed comments for use in the SAMPLE PROGRAMMING Screen. Comments may be modified at any time.

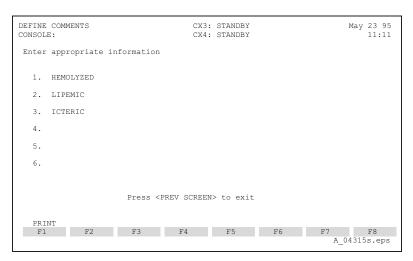
- From the MASTER Screen, press F4 SPECIAL FUNCTION.
- Cursor and SELECT 4. System Setup, or type 4 ENTER.
- Cursor and SELECT 12. Define Comments, or type 12 ENTER. The DEFINE COMMENTS Screen is displayed.



4. The cursor is active at the first input field. Comments may be defined or edited at any input field. Type a comment of up to 25 characters. Press ENTER or Up/Down arrow key to save the comment.



- Use ENTER or the Up/Down cursor arrow keys to move to another field if desired.
- 6. Press **F1 PRINT** to obtain a hard copy of the programmed comments.
- 7. Press **PREV SCREEN** to exit and return to the SYSTEM SETUP display, or **MASTER SCREEN** to return to the MASTER Screen.
- 8. All comments defined in DEFINE COMMENTS are available in the SAMPLE PROGRAMMING Screen by pressing F1 SELECT OPTIONS from the Comments field. In addition, a seventh comment (two lines, 25 characters each) is available for free text input.

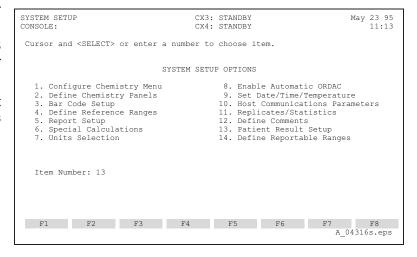


6.5.1.13 Patient Result Setup

6.5.1.13.1 Result Approval For Host

This option enables the operator to determine if results (both patient and QC) are sent to the host automatically or if the results are held until the operator reviews and approves the results to send to the host.

- 1. From the MASTER Screen, press **F4 SPECIAL FUNCTIONS**.
- From the SPECIAL FUNCTIONS Screen, SELECT 4. System Setup or type 4, then press ENTER.
- Cursor and SELECT 13. Patient Result Setup, or type 13, then press ENTER.



 At the Result Approval For Host line, press SELECT to enable or disable the option.

NOTE

If CX3 Immediate Output to Host is enabled, the system will not allow the operator to enable Result Approval For Host.

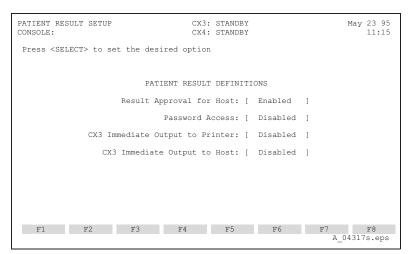
5. Press **PREV SCREEN** to return to the SYSTEM SETUP Screen, or press **MASTER SCREEN** to exit.

NOTE

If Result Approval For Host is enabled, results must be approved and sent to the host at regular intervals (at least daily) to avoid exceeding system storage capacity of pending host results.

NOTE

If Result Approval For Host is enabled, results must be approved and sent to the host, or the pending host status must be cleared (refer to paragraph 6.5.3.4) before rerunning or editing the sample.



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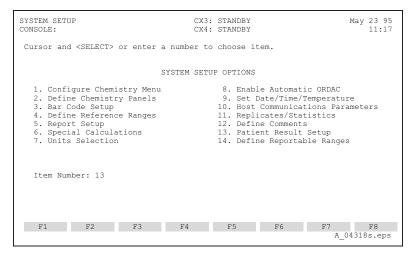
6.5.1.13.2 Password Access

This option allows the operator to enable or disable the requirement of a password for editing results; and approving results, if Result Approval For Host is also enabled. Once Password Access is enabled, this option also allows the user to define the passwords.

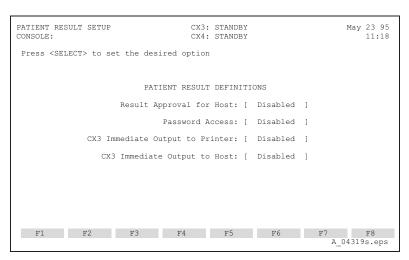
Access to this option requires an administrative password. Upon the initial setup of the system, this password is BECKMAN. It is recommended that the laboratory administrator/supervisor change the administrator password immediately, even if the Password Access is going to remain disabled. The administrator password should then be kept in a secure location.

Enable/Disable Password Access

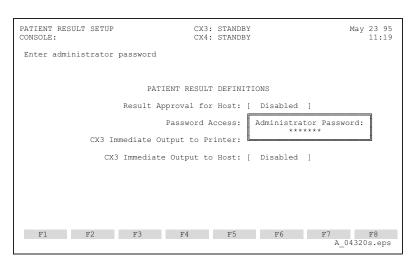
- From the MASTER Screen, press F4 SPECIAL FUNCTIONS.
- From the SPECIAL FUNCTIONS Screen, SELECT 4. System Setup or type 4, then press ENTER.
- Cursor and SELECT 13. Patient Result Setup, or type 13, then press ENTER.



 At the Password Access line, press SELECT to enable or disable the option.

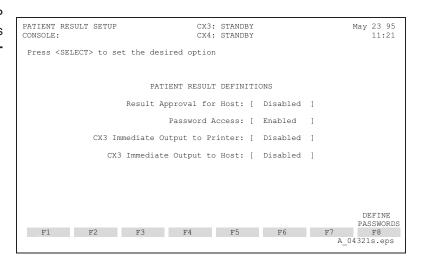


At the Administrator Password window, type in the appropriate password, then press ENTER.

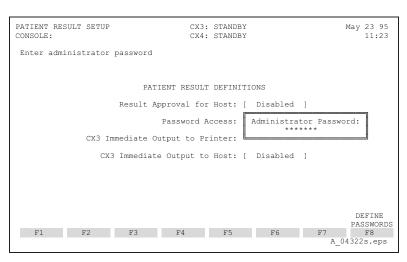


Define Passwords

 From the PATIENT RESULT SETUP Screen and with Password Access enabled, press F8 DEFINE PASS-WORD.



At the Administrator Password window, type in the appropriate password, then press ENTER.



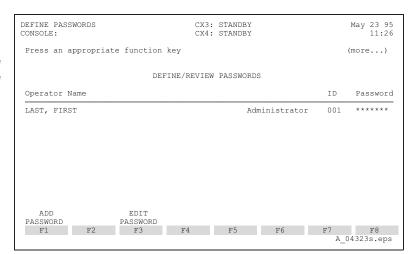
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3. Press the appropriate function key:

F1 ADD to add new passwords,

F2 DELETE to select passwords to be deleted (**F2 DELETE** is only available if passwords are defined), or

F3 EDIT to edit existing passwords.



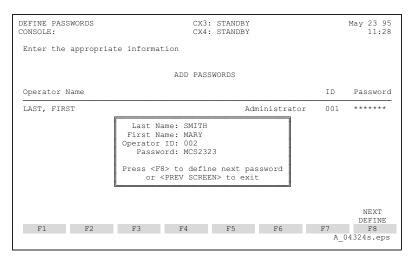
4. From the ADD PASSWORDS Screen, enter the appropriate information on each of the four lines. To add another password, press F8 NEXT DEFINE. When all passwords are defined, press PREV SCREEN to return to the DEFINE/ REVIEW PASSWORDS Screen, or press MASTER SCREEN to exit.

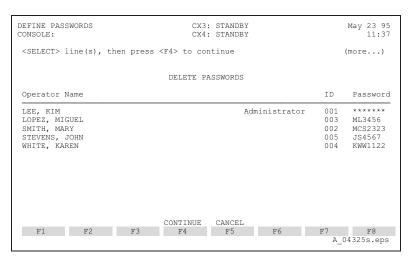
NOTE

Press **ENTER** after the last entry to save the information.

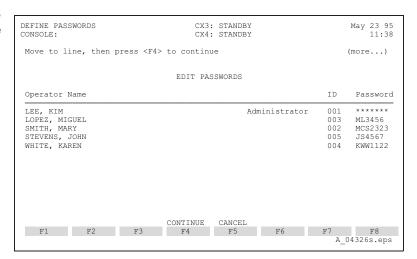
 From the DELETE PASSWORDS Screen, cursor and SELECT the lines to be deleted, then press F4 CON-TINUE to delete the lines. Press F5 CANCEL to deselect lines and return to the DEFINE/REVIEW PASS-WORDS Screen.

Press PREV SCREEN to return to the PATIENT RESULT DEFINITIONS Screen or MASTER SCREEN to exit.

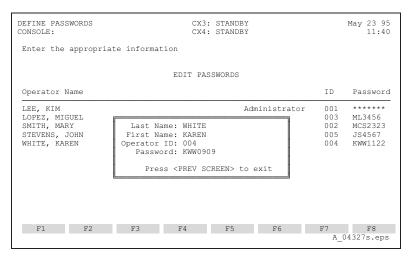




From the EDIT PASSWORDS Screen, cursor and SELECT the line to be edited.



7. With the EDIT Window open, cursor to the line of information to be edited and enter appropriate information. All lines must be complete for the information to be saved. When editing is complete, press PREV SCREEN to return to the DEFINE/REVIEW PASSWORDS Screen, or press MASTER SCREEN to exit.



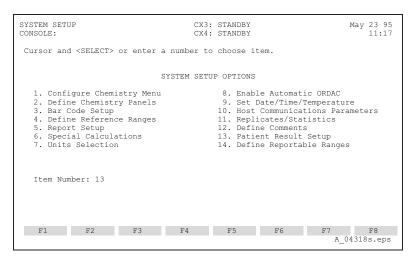
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6.5.1.13.3 CX3 Immediate Output to Printer and Host

This option allows the operator to determine when complete CX3 results are sent to the printer and host. CX3 results can be sent: 1) for all CX3 chemistries as soon as they are complete, 2) for only STAT requests, or 3) when the entire CX7 report is generated.

Chemistries from the CX4 which are not complete at the time of an interim report are designated by the message "RESULTS NOT AVAILABLE" in place of results. The interim report includes any results for the CX4 that are complete at the time the report is generated. A final report with both the CX3 and CX4 results is printed upon completion of the sample.

- From the MASTER Screen, press F4 SPECIAL FUNCTIONS.
- From the SPECIAL FUNCTIONS Screen, SELECT 4. System Setup or type 4, then press ENTER.
- Cursor and SELECT 13. Patient Result Setup, or type 13, then press ENTER.



4. At the CX3 Immediate Output to Printer or CX3 Immediate Output to Host line, press SELECT to choose between:

Disabled, to hold printing and/or host transmittance of the report until all CX7 results are complete;

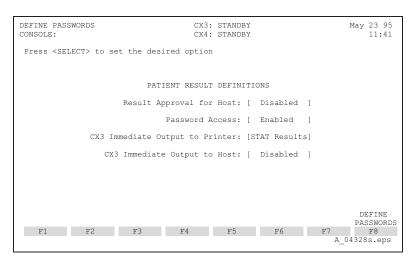
STAT Results, to print and/or send to host an interim report with CX3 STAT results when complete; or

All Results, to print and/or send to host an interim report for all CX3 results when complete.

 Press PREV SCREEN to return to the SYSTEM SETUP Screen, or press MASTER SCREEN to exit.

NOTE

If Result Approval For Host is enabled, the system will not allow the operator to enable CX3 Immediate Output to Host.

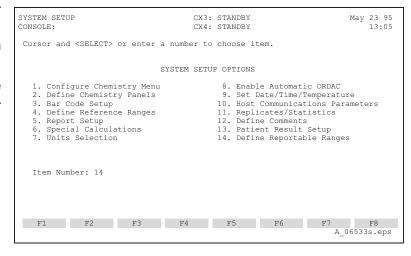


6.5.1.14 Define Reportable Ranges

This option allows the user to define the reportable range for each chemistry configured on their system. It is recommended that each facility establish reportable ranges based on its own studies for each chemistry. The default reportable range is the instrument printable range. Instrument printable ranges and reportable ranges may be viewed by the operator while the system is running. To establish or edit the reportable ranges the system must be in Standby.

Defining Reportable Ranges

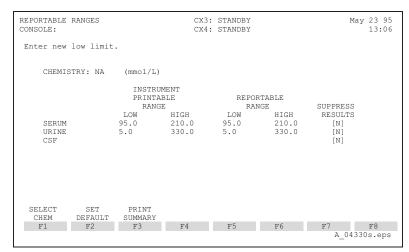
- From the MASTER Screen, press F4 SPECIAL FUNCTION.
- 2. Cursor and **SELECT 4**. System Setup, or type **4** then **ENTER**.
- Cursor and SELECT 14. Define Reportable Ranges, or type 14 ENTER.



4. The first configured chemistry with currently defined units, instrument printable and reportable ranges and ORDAC ranges, if applicable, is displayed on the initial reportable range screen. Before modification, the reportable range will be set to the default instrument printable range for all chemistries. To display the screen for a different chemistry press F1 SELECT CHEM.

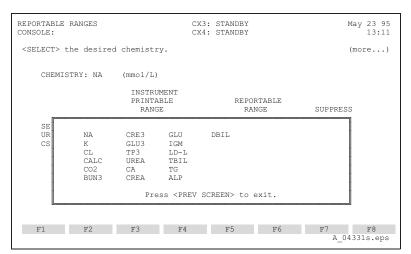
NOTE

To accommodate for the imprecision of the assays at the upper and/or lower end of the analytic range, the printable range may slightly exceed the claimed analytic range.

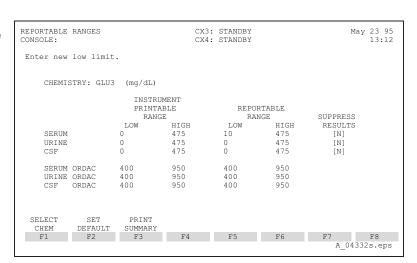


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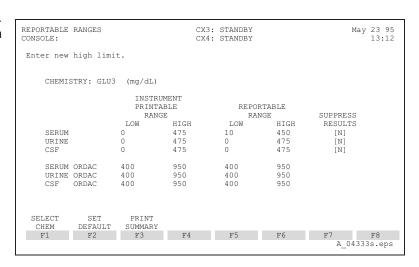
 Cursor and SELECT desired chemistry. The Chemistry selection window closes and the cursor is displayed at the low field for the reportable range for serum.



 Enter the low reportable range value.
 ENTER or the arrow keys enters the value and moves the cursor.



7. Enter the high reportable range value. The high value must be greater than the low value.



NOTE

The HIGH ORDAC reportable range value will be automatically evaluated and changed, if indicated, when the high reportable range is redefined by the user for that sample type. The LOW ORDAC reportable range is fixed at the lowest printable range.

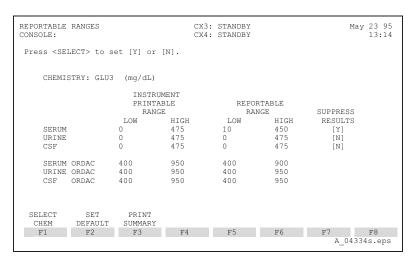
 The cursor will now be active in the Suppress results field. Toggle between "Y" and "N" with the SELECT key.

NOTE

This function gives the operator the option of suppressing results which fall outside the limits of the user defined reportable range. Results outside the instrument printable range will always be suppressed. Suppress Results field will always default to "N".

NOTE

If the operator selects not to suppress results that are outside the reportable range, certain report formats will print the result without the ORR (outside reportable range) flag. These report formats are Chart Format B, the Result Summary Report and the Patient Multi-Sample Report. In addition the Control Report will not print the ORR flag if standard deviation, accuracy or precision flags are triggered as these take precedence.



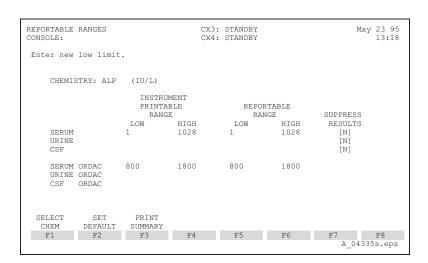
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9. To continue entering ranges for additional sample types for a chemistry, press ENTER, the Right arrow key or the Down arrow key to move to the next input line. Be sure to press ENTER after the last entry before exiting this chemistry screen tot save the information.

NOTE

The instrument printable range for certain sample types may be blank. This indicates that the chemistry is not validated by BECKMAN for that sample type. Although the user can enter reportable ranges for any sample type, it is suggested that chemistry validation tests be performed and documented by the user's facility before these sample types are utilized for patient testing.

- To return reportable range values to the instrument default printable ranges cursor to the appropriate field(s) and press F2 SET DEFAULT.
- 11. To continue defining ranges for other chemistries, press F1 SELECT CHEM and repeat steps 5 through 8. To exit Define Reportable Ranges, press PREV SCREEN to return to the SYSTEM SETUP Screen or press MASTER SCREEN to return to the MASTER Screen.
- 12. To delete a previously entered reportable range value, cursor to the appropriate field and press CLEAR. If the sample type is validated by BECK-MAN and has corresponding instrument printable range values, the reportable range must have information entered (it cannot be left blank), Select F2 SET DEFAULT or enter new values.



13. To obtain a Reportable Range Summary, press F3 PRINT SUMMARY. This functions provides a hard copy summary of all configured chemistries and their instrument printable ranges, reportable ranges, ORDAC ranges and suppressed results designations for all sample types which have reportable range values. Refer to Figure 6-11

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SYNCHRON CX7 DELTA REPORTABLE RANGE SUMMARY

CHEM		SAMPLE	INSTRUMENT PRINTABLE	REPORTABLE	SUPPRESS
		TYPE	RANGE	RANGE	RESULTS
	(mmol/L)		95.0 - 210.0	95.0 - 210.0	No
		Urine	5.0 - 330,0	5.0 - 330.0	No
К	(mmol/L)		0.70 - 15.50	0.70 - 15.50	No
		Urine	1.00 - 330.00	1.00 - 330.00	No
CL	(mmol/L)		45.0 - 210.0	45.0 - 210.0	No
		Urine CSF	10.0 - 440.0 45.0 - 210.0	10.0 - 440.0 45.0 - 210.0	No No
CALC	(mg/dL)	Cause	4 5 47 4		
CALC	/mg/or/	Urine	1.5 - 16.1 1.5 - 16.1	1.5 - 16.1 1.5 - 16.1	No No
					140
COS	(mmol/L)	Serum	3.0 - 55.0	3.0 - 55.0	No
BUN3	(mg/dL)		0.0 - 160.0	0.0 - 160.0	No
15 LINES	OPPOC	Urine	0.0 - 160.0	0.0 - 160.0	No
BUNG	ORDAC	Serum Urine	130.0 - 320.0 130.0 - 320.0	130.0 - 320.0	
		Orthe	130.0 - 320.0	130.0 - 320.0	
CRE3	(mg/dL)		0.00 - 27.00	0.00 - 27.00	No
	÷	Urine	8.00 - 430.00	8.00 - 430.00	No
GLU3	(mg/dL)	Serum	Ø - 475	10 ~ 450	Yes
		Urine	0 - 475	10 - 450	Yes
CL 113	ODDAG	CSF	Ø - 475	10 - 450	Yes
GEUS	ORDAC	Serum Urine	400 - 950	400 – ୨ ଉପ	
		CSF	400 - 950 400 - 950	400 - 900	
		Cor	400 - 950 1	4ଉଉ – ୨ଉଉ	
TP3	(g/dL)		2.5 - 12.5	2.5 - 12.5	No
	(mg/dL)	CSF	5.0 - 790.0	5.0 - 790.0	No ·
UREA	(mmol/L)		0.3 - 37.1	Ø.3 - 37.1	No
		Urine	0.3 - 37.1	0.3 - 37.i	No
CA	(mg/dL)		1.6 - 15.6	1.6 - 15.6	No
		Urine	1.6 - 15.6	1.6 - 15.6	No
CREA	(mg/dL)	Serum	0.00 - 26.50	0.00 - 26.50	No
		Urine	6.00 - 424.00	6.00 - 424.00	No
GLU	(mg/dL)	Serum	1 - 728	1 - 728	No
		Urine	1 - 728	1 - 728	No
		CSF	1 - 728	1 - 728	No
IGM	(mg/dL)	Serum	15 - 350	15 - 350	No
					A_05084C.EPS

Figure 6-11. Reportable Range Summary

6.5.2 Prime

6.5.2.1 System Module Prime

This feature allows the user to manually prime the following CX3 and CX4 modules. The Prime option is only active when the system is in Standby.

NOTE

Priming the CX4 while the CX3 Module is running may interrupt CX3 samples being processed.

CX4

External Probe Wash Washes outside of sample and reagent probes with diluted wash

concentrate.

Internal Probe Wash Primes inside of reagent probe with DI water and probe rinse solution

and sample probe with DI water.

Cuvette Wash Lines Primes wash lines 1 and 2 with wash solution and lines 3 and 4 with DI

water.

Drain Pump Evacuates residual waste from the drain pump

Fill Wash Bottles Fills the two wash bottles with diluted wash.

All Hydropneumatic Modules Primes all of the above.

CX3

CX3 BUN Primes the CX3 BUN reagent.

CX3 GLU Primes the CX3 Glucose reagent.

CX3 CRE Primes the CX3 Creatinine reagent.

CX3 CA or CX3 TP Primes the CX3 Calcium or CX3 Total Protein reagent.

Wash Solution Runs the Wash and Drain peri-pump to prime wash solution through

the injection cup and out the drain.

Ratio Pump Primes the CX3 Ratio Pump.

Electrolyte Reference/ Flow Cell Primes the CX3 Electrolyte Reference peri-pump with undiluted

reference solution

Electrolyte Reference Ratio Pump Primes the Electrolyte Reference solution through the first stage of the

ratio pump and the sample probe

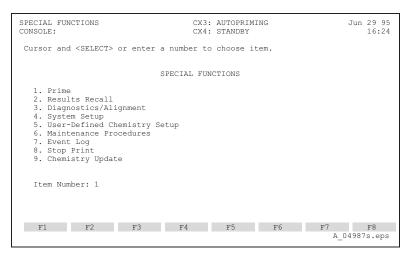
CO₂ Alkaline Buffer Primes the Alkaline Buffer peri-pump with CO₂ Alkaline Buffer

Reagent.

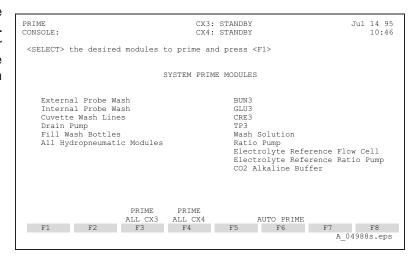
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Priming the System Modules

- From the MASTER Screen, press F4 SPECIAL FUNCTION.
- Cursor and SELECT 1. Prime, or type 1 ENTER.



 Press F3 PRIME ALL CX3 to prime all CX3 modules; or F4 PRIME ALL CX4 to prime all CX4 modules; or move cursor to the module to be primed and press SELECT. More than one module may be primed at a time.

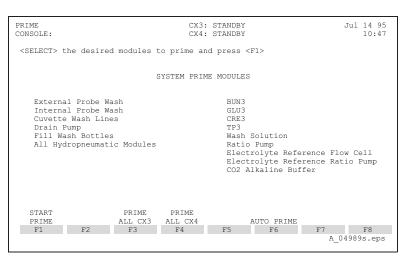


 When selections are complete, press F1 START PRIME. The operator is prompted to enter the number of CX3 primes desired (CX4 priming cycles are automatically set).

NOTE

No other priming selections are permitted until priming is complete.

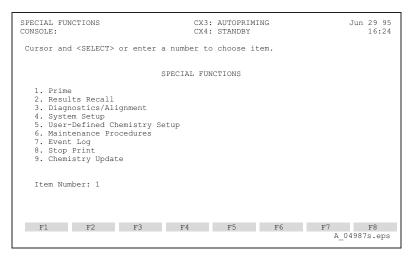
- 5. Press **F2 STOP PRIME** to terminate priming before completion.
- 6. Press PREV SCREEN or MASTER SCREEN to exit.



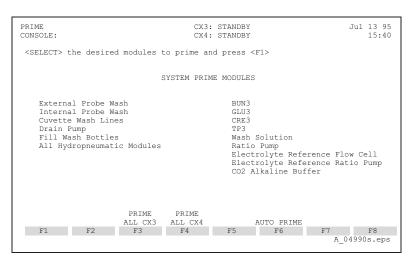
6.5.2.2 Auto Prime

This feature allows the operator to set the system to automatically prime the hydropneumatic modules after the system has been idle (STANDBY) for a specified time interval.

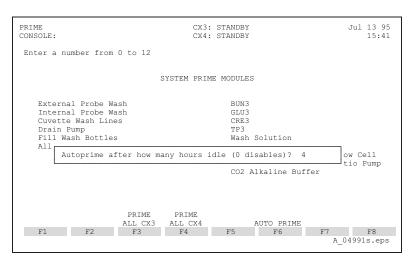
- 1. From the MASTER Screen, press **F4 SPECIAL FUNCTION**.
- Cursor and SELECT 1. Prime, or type 1 and press ENTER.



3. Press F6 AUTO PRIME.



- 4. Type the time interval, (0-12) hours, of idle time (system not running) that will elapse before an autoprime occurs. The default is 0, which disables autoprime.
- Press PREV SCREEN or MASTER SCREEN to exit.



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6.5.3 Results Recall

This option enables the user to recall completed results by sector number, sector/cup number, sample ID, patient ID, patient name, queue position, doctor name or control name, and then output the information to the monitor (display on the CRT), the printer, or retransmit the results to a host computer. This feature can also be used to recall results prior to a completed collated report; however, any chemistries which are not complete will be flagged. If multiple replicates are available for recall, the last replicate is displayed first (eg. rep 3, rep 2, rep 1). The Edit Results function is accessed through Results Recall (refer to paragraph 6.5.3.5).

Results Recall Menu is also used to recall and print the Patient Multi-sample Report and to access Meter Information and Approve Results, if enabled. Recall can be accessed at all times.

NOTE

The system retains a maximum of 10,000 results and 2,000 sample programs. Once these limits have been exceeded, the system will chronologically overwrite existing results.

Once a sample program has been cleared, results cannot be recalled by sample ID.

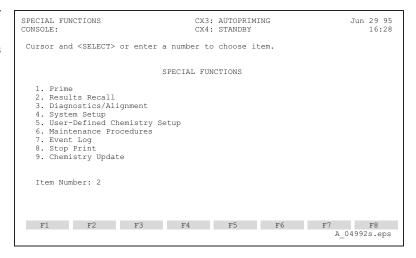
6.5.3.1 Recall Options

Recall by Sector

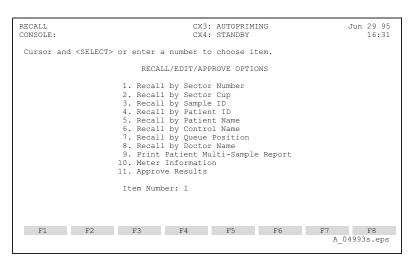
NOTE

Results may be recalled by sector as long as the sector has not been cleared.

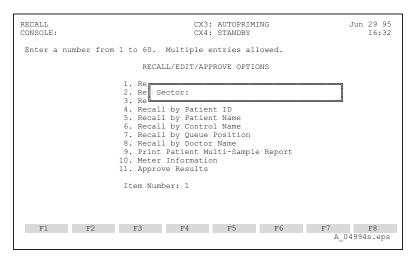
- From the MASTER Screen, press F4 SPECIAL FUNCTION.
- 2. Cursor and **SELECT 2**. Results Recall, or type **2 ENTER**.



3. Cursor and **SELECT 1**. Recall by Sector Number, or type **1 ENTER**.



4. Enter the sector number to be recalled. Multiple entries are allowed (Enter a number range separated by a dash, or enter discreet numbers separated by commas). Results for the cups currently assigned to the sectors requested will be retrieved.



5. Go to Paragraph 6.5.3.2 for output options.

NOTE

If no results are available for the sector requested, the message NO DATA AVAILABLE is displayed in the message area of the screen.

If a result is larger than the display field, the "@" character is displayed.

NOTE

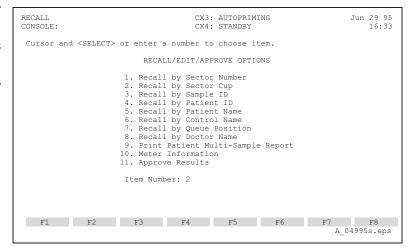
For DAT chemistries, the cutoff value is stored with the result and is not overwritten with subsequent calibration. However, in sector/cup mode the cutoff value is overwritten if the sector/cup is rerun with a new calibration.

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NOTE

Results may be recalled by sector as long as the sector has not been cleared.

- 1. From the MASTER Screen, press **F4 SPECIAL FUNCTION**.
- 2. Cursor and **SELECT 2**. Results Recall, or type **2 ENTER**.
- 3. Cursor and **SELECT 2**. Recall by Sector/Cup, or type **2 ENTER**.

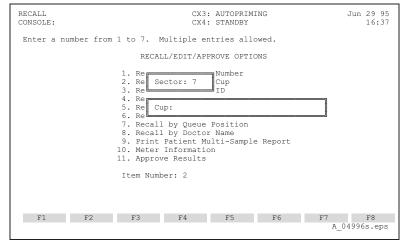


- Enter the sector number to be recalled.
- Enter the cup positions to be recalled.
 Multiple entries are allowed (Enter a
 number range separated by a dash,
 or enter discreet numbers separated
 by commas).
- 6. Go to Paragraph 6.5.3.2 for output options.

NOTE

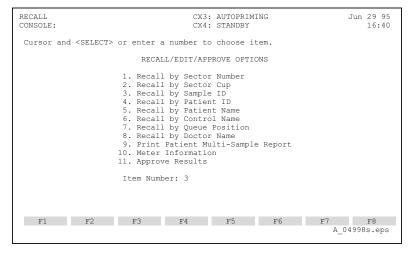
If no results are available for the Sample ID requested, the message NO DATA AVAILABLE is displayed in the message area of the screen.

If a result is larger than the display field, the "@" character is displayed.



Recall by Sample ID

- From the MASTER Screen, press F4 SPECIAL FUNCTION.
- 2. Cursor and **SELECT 2**. Results Recall, or type **2 ENTER**.
- From the RECALL Screen, cursor and SELECT 3. Recall by sample ID, or type 3 ENTER.

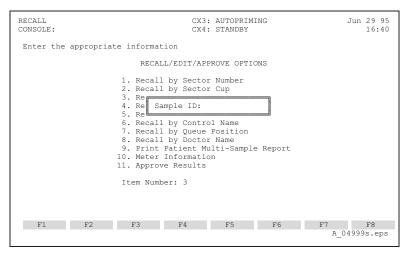


- Enter the sample ID to be recalled (all results associated with the sample ID entered will be recalled).
- 5. Go to Paragraph 6.5.3.2 for output options.

NOTE

If no results are available for Sample ID requested, the message NO DATA AVAILABLE is displayed in the message area of the screen.

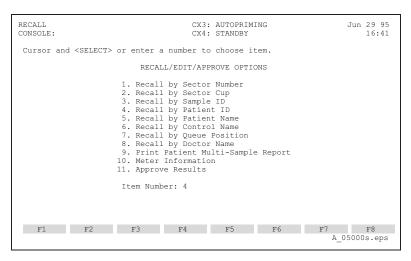
If a result is larger than the display field, the "@" character is displayed. Results may be recalled by sample ID as long as the sector, sample ID or queue number have not been cleared.



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Recall by Patient ID

- 1. From the MASTER Screen, press **F4 SPECIAL FUNCTION**.
- 2. Cursor and **SELECT 2**. Results Recall, or type **2 ENTER**.
- From the RECALL Screen, cursor and SELECT 4. Recall by Patient ID, or type 4 ENTER.

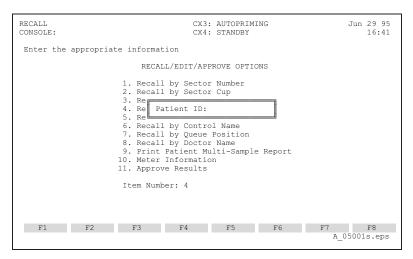


- Enter the patient ID to be recalled (all results associated with the patient ID entered are recalled).
- 5. Go to Paragraph 6.5.3.2 for output options.

NOTE

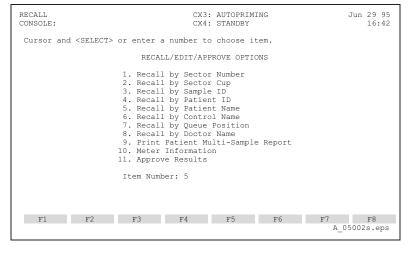
If no results are available for the Patient ID requested, the message NO DATA AVAILABLE is displayed in the message area of the screen.

If a result is larger than the display field, the "@" character is displayed.



Recall by Patient Name

- From the MASTER Screen, press F4 SPECIAL FUNCTION.
- 2. Cursor and **SELECT 2**. Results Recall, or type **2 ENTER**.
- From the RECALL Screen, cursor and SELECT 5. Recall by Patient Name, or type 5 ENTER.

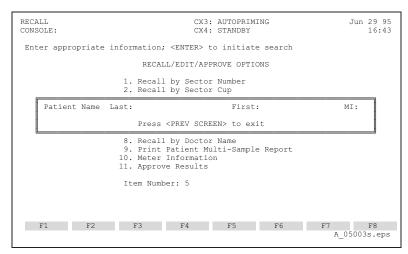


- 4. In the window provided, enter the patient name to be recalled (all results associated with the patient name entered are recalled). Use upper case letters.
- 5. Go to Paragraph 6.5.3.2 for output options.

NOTE

If no results are available for the Patient Name requested, the message NO DATA AVAILABLE is displayed in the message area of the screen.

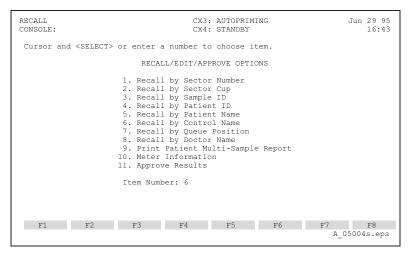
If a result is larger than the display field, the "@" character is displayed.



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Recall by Control Name

- 1. From the MASTER Screen, press **F4 SPECIAL FUNCTION**.
- 2. Cursor and **SELECT 2**. Results Recall, or type **2 ENTER**.
- From the RECALL Screen, cursor and SELECT 6. Recall by Control Name, or type 6 ENTER.



 The currently defined controls are displayed. Cursor and SELECT or enter the item number of the control to be recalled (all results associated with the control name entered are recalled).

NOTE

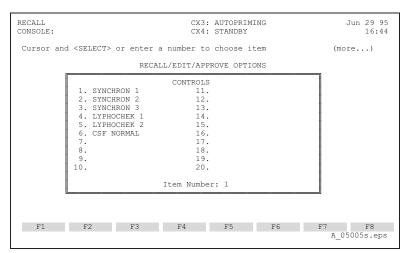
If a control has been cleared in Quality Control, Define/Review Controls, and then redefined using the same control name, results for both definitions may be available for recall.

5. Go to Paragraph 6.5.3.2 for output options.

NOTE

If no results are available for the Control Name requested, the message NO DATA AVAILABLE is displayed in the message area of the screen.

If a result is larger than the display field, the "@" character is displayed.



Recall by Queue Position

- From the MASTER Screen, press F4 SPECIAL FUNCTION.
- 2. Cursor and **SELECT 2**. Results Recall, or type **2 ENTER**.
- From the RECALL Screen, cursor and SELECT 7. Recall by Queue Position, or type 7 ENTER.
- CONSOLE: CX4: STANDBY 16:45

 Cursor and <SELECT> or enter a number to choose item.

 RECALL/EDIT/APPROVE OPTIONS

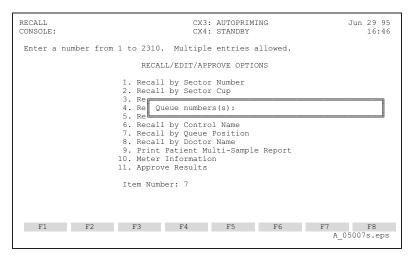
 1. Recall by Sector Number
 2. Recall by Sector Cup
 3. Recall by Sample ID
 4. Recall by Patient ID
 5. Recall by Patient Name
 6. Recall by Potorn Name
 7. Recall by Queue Position
 8. Recall by Doctor Name
 9. Print Patient Multi-Sample Report
 10. Meter Information
 11. Approve Results

 Item Number: 7
- 4. In the window provided, enter the queue positions to be recalled; multiple queue positions can be entered and are separated by commas or hyphens. All results associated with the queue positions entered are recalled.
- 5. Go to Paragraph 6.5.3.2 for output options.

NOTE

If no results are available for the Queue positions requested, the message NO DATA AVAILABLE is displayed in the message area of the screen.

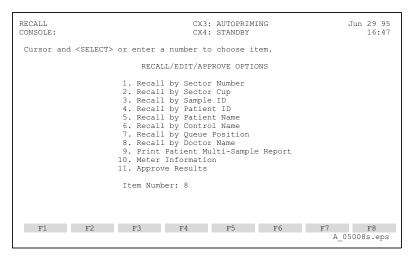
If a result is larger than the display field, the "@" character is displayed.



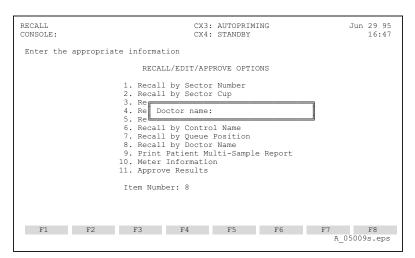
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Recall by Doctor Name

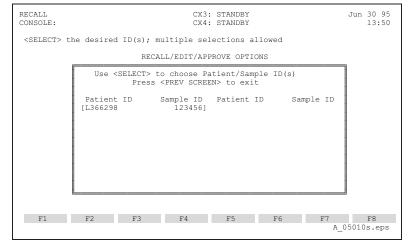
- From the MASTER Screen, press F4 SPECIAL FUNCTION.
- 2. Cursor and **SELECT 2**. Results Recall, or type **2 ENTER**.
- From the RECALL Screen, cursor and SELECT 8. Recall by Doctor Name, or type 8 ENTER.



In the window provided, enter the doctor name for which results are to be recalled.



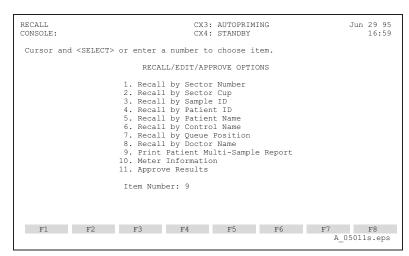
- A second window displays the patient IDs and sample IDs associated with the doctor's name. Cursor and SELECT the results to be recalled.
- When selections are complete, press PREV SCREEN to close the window and retrieve the requested results.
- 7. Go to Paragraph 6.5.3.2 for output options.



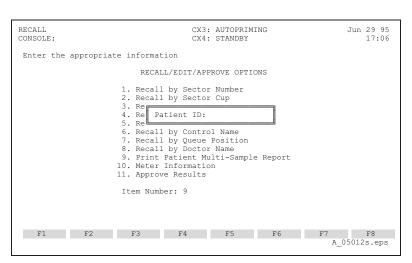
Printing the Patient Multi-Sample Report

The Patient Multi-Sample Report is a means of printing multiple results for a given patient ID on a single, condensed report. The result for each specific chemistry is calculated and printed to reflect the current unit selected for the test; all results for a given chemistry are in the same units. Because this report is based on Patient ID, operators must remember to enter a Patient ID when sample programs are created in order to exercise this option.

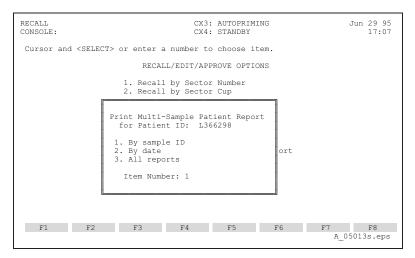
- From the MASTER Screen, press F4 SPECIAL FUNCTION.
- 2. Cursor and **SELECT 2**. Results Recall, or type **2 ENTER**.
- From the RECALL Screen, cursor and SELECT 9. Print Patient Multi-Sample Report, or type 9 ENTER.



 In the window provided, enter the Patient ID for which results are to be recalled.

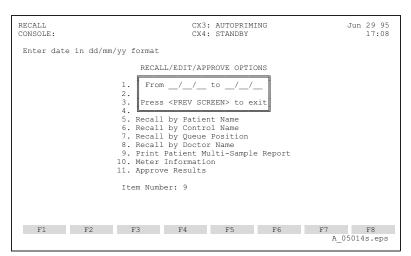


5. The report may be printed for a specified date range (proceed with Step 6), for specified Sample IDs (proceed to Step 7), or to include all reports associated with the Patient ID. Cursor and SELECT the option desired, or type the option number and press ENTER. If option 3. All is selected, the report will begin printing.

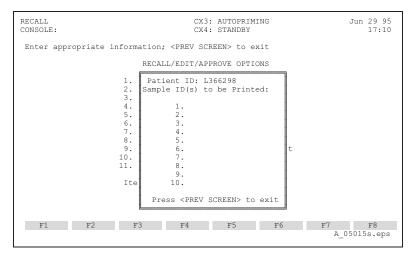


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If the report is defined by a date range, enter the dates at the prompt provided. Press ENTER to initiate printing of the report.

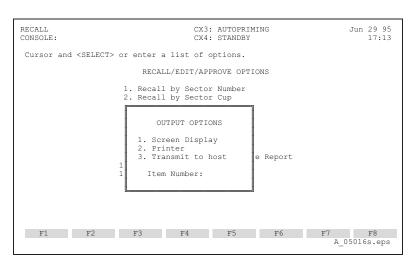


- 7. If specific Sample IDs are to be included in the report, enter up to 10 Sample IDs in the window provided. Press ENTER to initiate printing of the report.
- To print additional Patient Multi-Sample Reports, repeat Steps 3 through 6.
 To exit, press PREV SCREEN to return to the SPECIAL FUNCTIONS Screen or MASTER SCREEN to return to the Master Screen.



6.5.3.2 Output Options

 Make the desired selection from the RECALL Screen and enter the appropriate information (Paragraph 6.5.3.1). The Output option window is displayed.



(a) Output to Screen Only

Cursor and **SELECT 1**. Screen Display, or type **1 ENTER**.

The screen is cleared and result data is displayed. Data may be viewed one screen at a time, or automatic scrolling may be enabled by pressing F1 AUTO PAGE. Results are then scrolled every 10 seconds. Pressing F1 PAUSE PAGE disables automatic scrolling of data.

To obtain a hard copy of the recalled results displayed, press **F2 PRINT**. Although recalled replicates are displayed in descending order (rep3, rep2, rep1), they are printed in ascending order (rep1, rep2, rep3).

To transmit the recalled results displayed to the host, press **F3 HOST**.

To access ABSORBANCE vs TIME, press **F8 ABS PLOT** (refer to paragraph 6.5.3.3)

RECALL CONSOLE	E:					STANDBY STANDBY			Jun 29 95 17:27
Run Da Sec/Cu	ate/Tim up: 7/ e Type:	e: 14 Ju 1 Queu	ın 95/13:	55 Na Pa	ame: ,				(more)
CHEM D	OIL	RESULTS		UNITS		REMARKS			
	1.0		94 0.7 7.0 3.4 211 3.5 87	mg/dL mg/dL g/dL g/dL g/dL mg/dL mg/dL mmol/L mmol/L	_	LOW HIGH LOW CRITICAL	. HIGH		
AUTO	-	PRINT	HOST	EDIT					ABS PLOT
F1		F2	F3	F4	I .	F5	F6	F7 A_	F8 _05018s.eps

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(b) Print Option

Cursor and **SELECT 2**. Print Option, or type **2 ENTER**.

Recalled results are routed to the printer.

(c) Transmit to Host

Cursor and **SELECT 3**. Transmit to Host, or type **3 ENTER**.

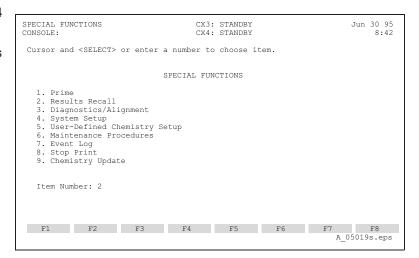
Recalled results are routed to the Host.

 Press PREV SCREEN to return to the main RECALL Screen, or press MAS-TER SCREEN to return to the MAS-TER Screen.

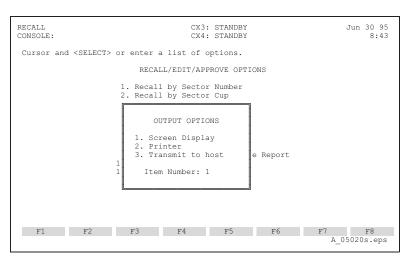
6.5.3.3 Absorbance versus Time

This option enables the operator to display and print Absorbance versus Time plots and tables from the Results Recall function. All complete CX4 chemistry results, including those associated with User Defined Reagents, will be available for this feature. Absorbance versus Time can be accessed at all times.

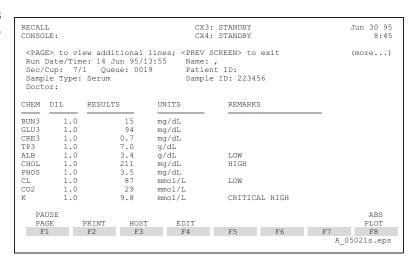
- From the MASTER Screen, press F4 SPECIAL FUNCTIONS.
- 2. Cursor and **SELECT 2.** Results Recall, or type **2**, then press **ENTER**.



 Cursor and SELECT the recall option desired as explained in section 6.5.3.1. SELECT 1. Screen Display, as the Output Option.



From the RECALL Screen, press F8
 ABS PLOT. The cursor will be active on the first applicable CX4 chemistry.



 Cursor and SELECT the desired chemistry results, up to a limit of 10.
 Use the PAGE keys to scroll results.
 When selections are complete, press:

F1 DISPLAY PLOT to display the first selected absorbance versus time plot;

F2 DISPLAY TABLE to display the first selected absorbance versus time table; or

F5 PRINT PLOT/TBL to print the plots and tables for all selected results.

6. If **F1 DISPLAY PLOT** is selected from step 5, press:

PAGE DOWN to view summary blank and reaction information.

F2 DISPLAY TABLE to display the corresponding absorbance versus time table.

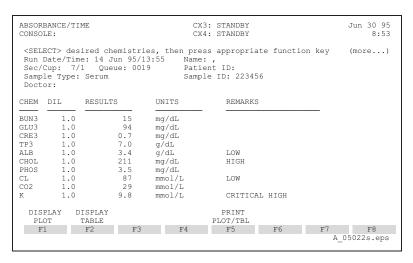
F3 NEXT PLOT to display the next selected chemistry absorbance versus time plot,

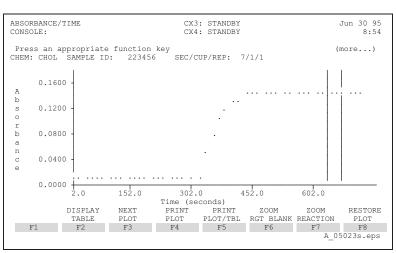
F4 PRINT PLOT to print the displayed plot,

F5 PRINT PLOT/TBL to print the displayed plot with corresponding table.

F6 ZOOM RGT BLANK to enlarge the reagent blank portion of the plot; or

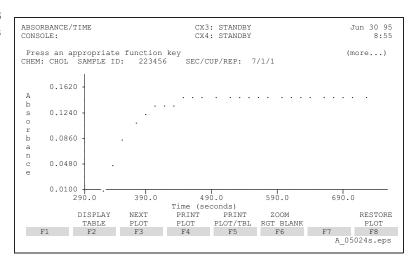
F7 ZOOM REACTION to enlarge the reaction portion of the plot.





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If the zoom function is used, press F8
 RESTORE PLOT to restore plot to its
 original and complete form.



- 8. If **F2 DISPLAY TABLE** is selected from step 5, press:
 - **F1 DISPLAY PLOT** to display the corresponding absorbance versus time plot;
 - **F3 NEXT TABLE** to display the next selected chemistry absorbance versus time table;
 - **F4 PRINT TABLE** to print the displayed table; or
 - **F5 PRINT PLOT/TBL** to print the displayed table with corresponding plot.

ABSORBANCE/TI CONSOLE:	ME			CX3: STANDBY		Ju	n 30 95 8:56
Press an app	ropriate f	unction	key			(mo	re)
CHEM: CHOL COMMENT:	ABSORBANC SAMPLE II	. ,		(X) TABLE SEC/CUP/REP: RUN/DATE/TIME:		95 13:55	
SECONDS A	BSORBANCE	SE	CONDS A	ABSORBANCE	SECONDS	ABSORBANCE	
3.0	0.00692		195.0	0.00713	387.0	0.12398	
19.0	0.00713	:	211.0	0.00713	403.0	0.13374	
35.0	0.00724	:	227.0	0.00734	419.0	0.13925	
51.0	0.00745		243.0	0.00724	435.0	0.14286	
67.0	0.00724		259.0	0.00702	451.0	0.14445	
83.0	0.00713		275.0	0.00755	467.0	0.14594	
99.0	0.00702	:	291.0	0.00734	483.0	0.14647	
115.0	0.00702		307.0	0.00734	499.0	0.14731	
131.0	0.00702		323.0	0.01317	515.0	0.14710	
147.0	0.00692		339.0	0.04859	531.0	0.14753	
163.0	0.00671		355.0	0.08327	547.0	0.14742	
179.0	0.00702		371.0	0.10903	563.0	0.14784	
DISPLAY		NEXT	PRINT	r PRINT			
PLOT		TABLE	TABLE	E PLOT/TBL			
F1	F2	F3	F4	F5	F6	F7	F8

NOTE

For UDR chemistries, the reaction read window in the User-Defined Chemistry Setup function will be 320 seconds less than the values in the absorbance versus time plots and tables for that chemistry. This occurs because absorbance versus time is recorded in absolute time while the User-Defined Chemistry Setup time is relative to the reagent inject.

NOTE

For UDR chemistries, the read window lines will reflect the currently defined parameters for the blank and reaction windows. If these parameters are changed and a previously run sample is recalled, the read windows will be drawn according to the new parameters. The original result, however, will not be altered even though the read windows may appear different than the original absorbance versus time plot. Occasionally, an altered reaction read window may not appear on the plot of a previously run sample as the x-axis is scaled to the data.

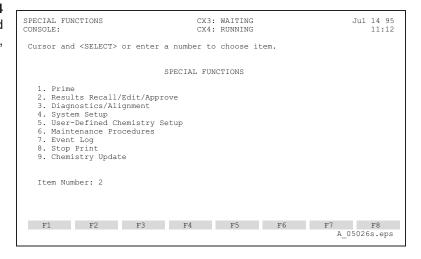
NOTE

Due to resolution limitations for the plot screen displays, some points may not display, or appear sightly different than the printed plot.

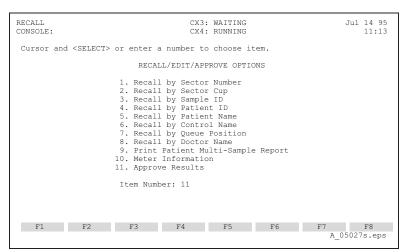
6.5.3.4 Approve Results

This option, if enabled in System Setup, allows the operator to view results before they are sent to the host. Only results from sample programs that qualify to be sent to the host and that have not already been sent to the host can be accessed through this function.

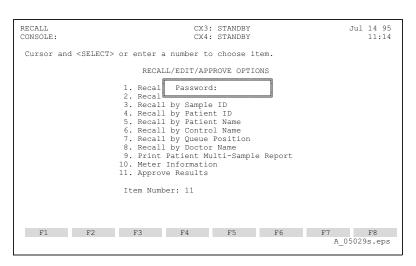
 From the MASTER Screen, press F4 SPECIAL FUNCTIONS. Cursor and SELECT 2. Results Recall, or type 2, then press ENTER.



 Cursor and SELECT 11. Approve Results or type 11, then press ENTER. ENTER the password, if enabled, or initials.

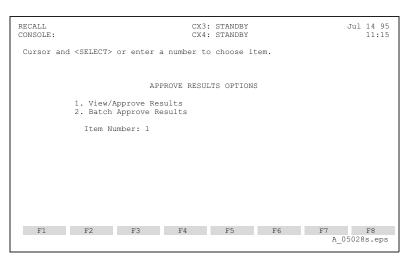


ENTER the password, if enabled, or initials.



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4. SELECT 1. View/Approve Results to view on the recall screen those complete results ready to be sent to host. SELECT 2. Batch Approve Results to send all complete results to the host without viewing on the screen.



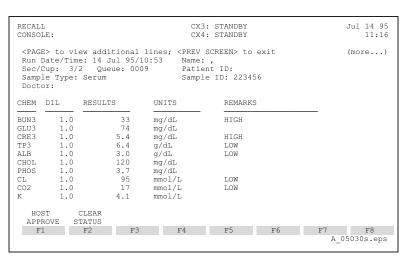
- 5. As each sample program with results is displayed, use PAGE keys to display additional results; F1 HOST APPROVE to send the currently displayed sample to the host; or F2 CLEAR STATUS to remove the currently displayed sample from the Approve Results option. These results can be recalled through recall functions 1-8 and sent to the host at a later time.
- Any samples not cleared through F2 CLEAR STATUS or F1 HOST APPROVE will remain in the Approve Results option and be displayed the next time the option is used.

NOTE

To edit results, first clear the pending host status by pressing **F2 CLEAR STATUS**. Recall results through applicable recall option (refer to paragraph (6.5.3.1) and edit the results (refer to paragraph 6.5.3.5).

NOTE

To rerun completed samples, first clear the pending host status by pressing F2 CLEAR STATUS.



6.5.3.5 Edit Results

The edit option enables the operator to edit SYNCHRON results and Sample Comments. The system reevaluates the edited results against the reference ranges and applies appropriate flags, if indicated. Any affected special calculations are recalculated. The option also enables the operator to append off-line results and special calculations to the report. All edited results are flagged by instrument codes on all reports and by (E) after the result on the recall screen and laboratory format reports. All off-line results are designated by a "-" (dash) before the chemistry or special calculation name. Off-line results are not sent to the host. Sample programs which have been cleared may not be edited.

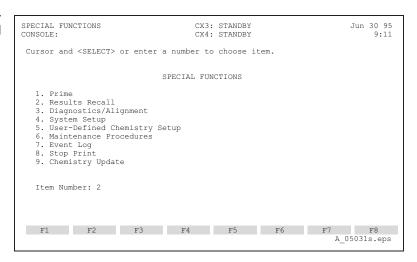
NOTE

Results may not be edited until the sample program has attained a complete status (sample off-loaded, results sent to host and printed). If the printer is off-line or jammed, whereby printing is prevented, the situation must be corrected before the sample program is available for result editing. If results are pending approval (Result Approval for Host enabled), press **F2 CLEAR STATUS** in the Result Approval screen or **F5 CLEAR STATUS** in the Recall screen to clear the pending host approval status.

NOTE

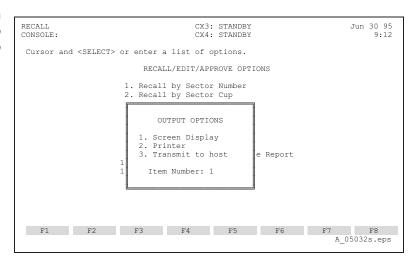
If a suppressed result is edited and the operator decides to restore the original suppressed status by pressing **F4 RESTORE RESULTS**, the operator must then press **F3 UPDATE REMARKS** to reinsert the SUPPRESSED comment. **PREV SCREEN** to the RECALL Screen will also correctly insert the comment. The operator should <u>never</u> use the Editing Screen to report clinical results, as this screen may or may not be fully updated depending on the actions of the operator. Use the RECALL Screen to display results for reporting.

 From the MASTER Screen, press F4 SPECIAL FUNCTIONS. Cursor and SELECT 2. Results Recall, or type 2, then press ENTER.



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2. Cursor and **SELECT** the recall option and enter applicable information to recall the results desired (refer to paragraph 6.5.3.1).

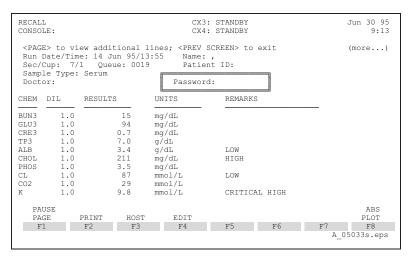


 With the sample program results displayed, press F4 EDIT. Type the password, if enabled, or initials, then press ENTER.

If Result Approval for Host is enabled, the following function Keys will be available:

F3 HOST APPROVE to approve and send results to the host.

F5 CLEAR STATUS to clear the pending host approval status. This is necessary to edit or rerun the sample.



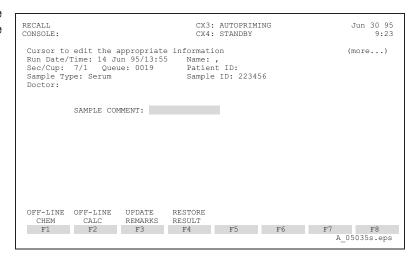
- Cursor to the SYNCHRON result(s) to be edited and type in the new value(s) and press ENTER.
 - **F4 RESTORE RESULT** will restore the result, where the cursor is located, to the SYNCHRON generated result.

NOTE

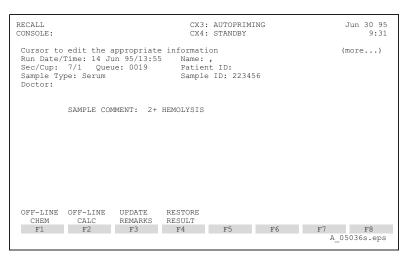
The result field cannot be left blank. The operator must enter a result or schedule a rerun of the test through sample programming. The later option will delete the result and place "No Results Available" in Remarks column.

If applicable, PAGE DOWN to the Sample Comment field and type in the desired comment and press ENTER.

RECALL CONSOLI					: STANDBY : STANDBY	Jun 30 95 9:21		
Run Da Sec/Ci	ate/Tim up: 7/ e Type:	ne: 14 Ju 1 Queu	ın 95/13:	te informat: 55 Name: Patie: Sample	nt ID:	56	(1	more)
CHEM I	DIL	RESULTS	3 1	UNITS	REMARK	S		
BUN3	1.0		 15 i	mg/dL				
GLU3	1.0		94 1	mg/dL				
CRE3	1.0		0.7	mg/dL				
TP3	1.0			g/dL				
ALB	1.0		3.1	g/dL	LOW			
	1.0			mg/dL	HIGH			
PHOS	1.0			mg/dL				
	1.0			mmol/L	LOW			
	1.0			mmol/L				
K	1.0		9.8	mmol/L	CRITICA	AL HIGH		
OFF-L	INE OF	F-LINE	UPDATE	RESTORE				
CHE	M	CALC	REMARKS	RESULT				
F1		F2	F3	F4	F5	F6	F7	F8
							A_05	034s.eps



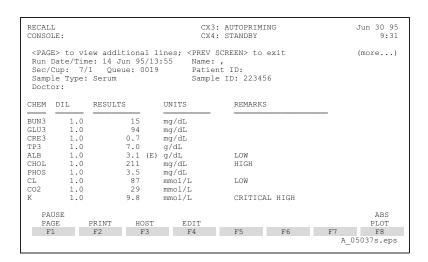
- 6. When complete, press:
 - **F1 OFF-LINE CHEM** to append off-line results to the report;
 - **F2 OFF-LINE CALC** to append offline special calculations to the report; or
 - the screen to show new applicable remarks. If editing is complete, press **PREV SCREEN** to update instrument codes and recalculation of on-line system special calculations. The screen will return to the Recall Screen in step 3, so that more results can be viewed with the **PAGE** keys, sent to the host, printed, or edited.



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NOTE

All edited results will display (E) after the result on the recall screen and laboratory report formats. An instrument code "Z" will be displayed with applicable chemistry codes on all reports.



- 7. If F1 OFF-LINE CHEM or F2 OFF-LINE CALC is chosen, a window will appear with fields for entering chemistry name, results, units, reference range and remarks. Cursor to these fields and type in the information. The chemistry name and results field must be completed in order for the information to be saved. Up to 10 off-line chemistries or calculations can be added.
- Press PREV SCREEN when complete. The screen will return so that the options in step 4 are accessible. Press F3 UPDATE REMARKS or PREV SCREEN to refresh the screen.

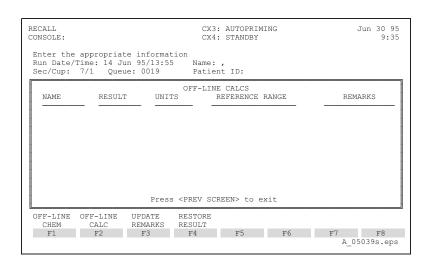
NOTE

Off-line result entry is designed for facilities without host systems. This feature enables the operator to produce a collated report with non-SYNCHRON generated results. Off-line results are not sent to the host.

NOTE

To clear previously entered information from Off-line chem or calc, move the cursor to each field and press the **CLEAR** key.

RECALL CONSOLE:				: AUTOPRIMI : STANDBY	ING	Jun 30 9:	
Run Date/	appropriat Time: 14 Ju 7/1 Queu	n 95/13:55	Name:				_
NAME	RESULT	UNIT	OFF-LIN	E CHEMS REFERENCE F	RANGE	REMARKS	7
		Press	<prev sc<="" td=""><td>REEN> to ex</td><td>kit</td><td></td><td></td></prev>	REEN> to ex	kit		
OFF-LINE CHEM F1	OFF-LINE CALC F2	UPDATE REMARKS F3	RESTORE RESULT F4	F5	F6	F7 F8	
2.1		10	2 1	2.5	2.0	A_05038s.eps	3



6.5.4 Event Log

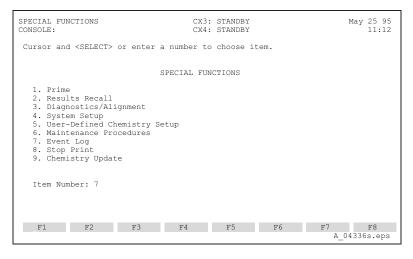
The event log records information about the system events listed in Table 6-16 and stores the information with the time and date at which the event occurred. This data is periodically copied to the system hard disk so that it will be available for troubleshooting and diagnostics. The event log records the 2000 most recent occurrences of events 2-22, and the 2000 most recent keystrokes (event 1). Event Log can be accessed at any time.

Table 6-16. List of Logged Events

1.	Keystrokes	12.	Calibration
2.	Special Calculations	13.	Sample Programming
3.	CX3 Instrument	14.	Quality Control
4.	CX4 Instrument	15.	Reagent Load
5.	Database Manager	16.	Setup
6.	Display Manager	17.	Prime
7.	Scheduler/Tube Addition	18.	Diagnostics/Maintenance
8.	Printer	19.	Sample Wheel Status
9.	Host Communications	20.	Event Logger/System
10.	Results Handler	21.	SCSI Communications
11.	Results Recall	22.	SCSI Messages

Reviewing an Event

- 1. From the MASTER Screen, press **F4 SPECIAL FUNCTION**.
- 2. Cursor and **SELECT 7**. Event Log, or type **7 ENTER**.

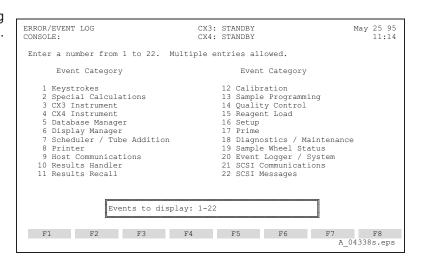


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 The ERROR/EVENT LOG Screen displays a list of event types that the system records. To display a particular category of events, press F1 DIS-PLAY EVENTS.

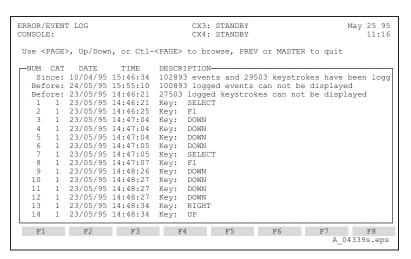
```
ERROR/EVENT LOG
                                            CX3: STANDBY
                                                                                   May 25 95
CONSOLE:
                                           CX4: STANDBY
                                                                                        11:13
 Press an appropriate function key
                                                      Event Category
        Event Category
                                                 12 Calibration
    2 Special Calculations
3 CX3 Instrument
                                                 13 Sample Programming
14 Quality Control
15 Reagent Load
    4 CX4 Instrument
    5 Database Manager
6 Display Manager
                                                 16 Setup
17 Prime
                                                 18 Diagnostics / Maintenance
    7 Scheduler / Tube Addition
      Printer
                                                  19 Sample Wheel Status
   9 Host Communications
10 Results Handler
                                                 20 Event Logger / System
21 SCSI Communications
22 SCSI Messages
   11 Results Recall
  DISPLAY
               PRINT
                           CLEAR
                                      LOG TO
 F1 F2 F3
                                    F4 F5 F6 F7
                                                                               F8
A 04337s.eps
```

 Enter the item number corresponding to the event type and press ENTER. Multiple entries are allowed.



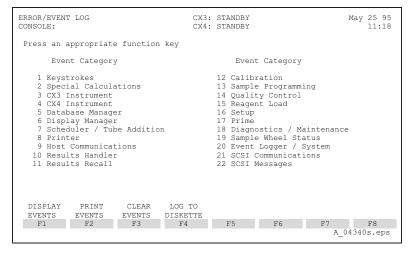
The system creates a file of the requested events and displays them in chronological order, newest events first.

Press **PREV SCREEN** to return to the main ERROR/EVENT LOG Screen.

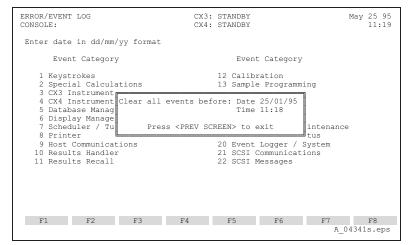


Clearing an Event

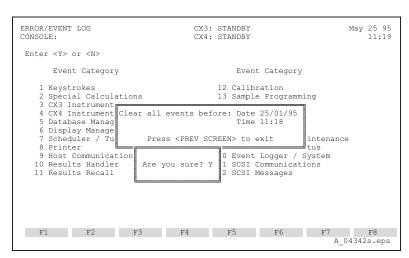
- From the MASTER Screen, press F4 SPECIAL FUNCTION.
- 2. Cursor and **SELECT 7**. Event Log, or type **7 ENTER**.
- 3. Press F3 CLEAR EVENTS.



4. A pop-up window prompts the operator for a date and time entry. All events prior to the date and time entered will be cleared. Enter the date in dd/mm/yy format, and the time in HH:MM format.



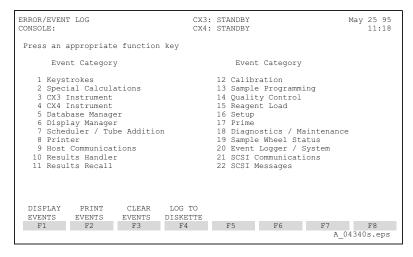
- 5. Confirm the request to clear by typing **Y**, **ENTER**.
- When events have been cleared, press PREV SCREEN to return to the main ERROR/EVENT LOG Screen.



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Logging Events to a Diskette

- From the MASTER Screen, press F4 SPECIAL FUNCTION.
- Cursor and SELECT 7. Event Log, or type 7 ENTER.
- 3. Press F4 LOG TO DISKETTE.



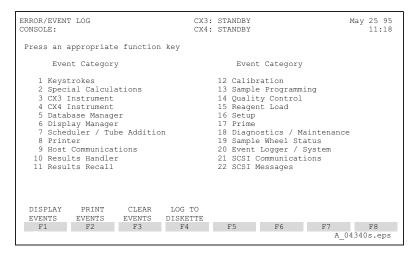
WARNING

Inserting the diskette will prepare the floppy disk by ERASING it before copying data.

- Insert a diskette into the drive and press ENTER to back up the events onto the diskette.
- When events have been backed up, press PREV SCREEN to return to the main ERROR/EVENT LOG Screen.

Printing Events

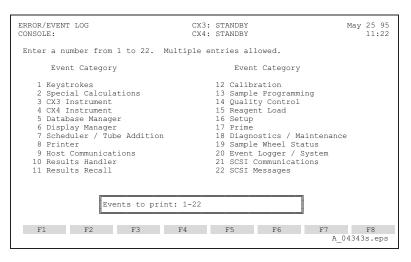
- From the MASTER Screen, press F4 SPECIAL FUNCTION.
- 2. Cursor and **SELECT 7**. Event Log, or type **7 ENTER**.
- 3. Press F2 PRINT EVENTS.



- 4. Enter the item number of the event file to be printed. Multiple entries are allowed. The log will be printed.
- Press PREV SCREEN to return to the SPECIAL FUNCTION Screen, or MASTER SCREEN to return to the MASTER Screen.

NOTE

To print specific event records, instead of the entire log, display the events through F1 DISPLAY EVENTS. Use PAGE UP/PAGE DOWN to display the desired screen. Press PRINT SCREEN to print the screen.



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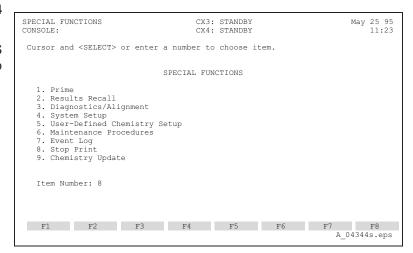
6.5.5 Stop Print

Stop Print is a feature which allows the operator to cancel print requests that have been queued to the printer. The CX4/CX7 queues print requests to the printer, then builds the report just before printing. Only one print request occupies the buffer at a time; this print request is called the "Current Print Task" on the STOP PRINT Screen. A lengthy report may occupy the entire printer buffer and be queued automatically by software via several requests. To interrupt a lengthy report, **F1 DELETE CURRENT** should be used. The current print buffer will print, but once exhausted, the report will stop printing.

Since only one report resides at a time in the printer buffer, additional requests are held in a print request queue. To cancel all print requests other than the current print task displayed, use **F2 DELETE ALL**. Cancelled print requests must be re-requested in order to be printed.

The displayed Print Task is not updated real-time. To display the current print task, use **F3 CURRENT TASK**. The screen will update to reflect the current task.

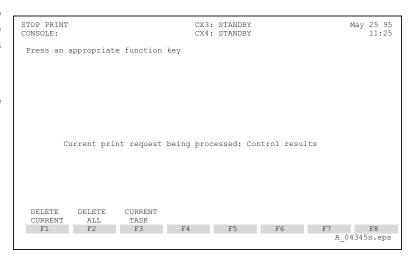
- From the MASTER Screen, press F4 SPECIAL FUNCTION.
- From the SPECIAL FUNCTIONS Screen, cursor and SELECT 8. Stop Print, or type 8 ENTER.



 All print requests currently queued to the printer are displayed. To stop printing of the current task as soon as the buffer is exhausted, press F1 DELETE CURRENT.

To cancel all print requests in the queue, press **F2 DELETE ALL**.

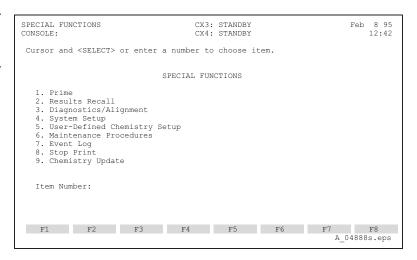
To update the screen for current task, press **F3 CURRENT TASK**.



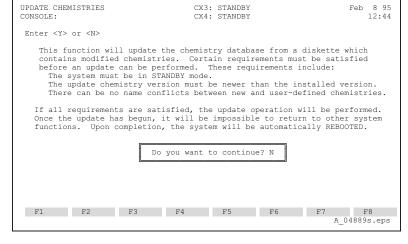
6.5.6 Chemistry Update

The Chemistry Update option allows operators to install newer chemistry database versions as they become available. The version to be installed must be newer than the version currently operating on the system. The instrument must be in Standby, and there can be no conflicts between new Beckman chemistry names and user defined chemistry names. The system will be rebooted at the conclusion of a successful chemistry database update. Reload calibration diskettes after chemistry updates.

- From the MASTER Screen, press F4 SPECIAL FUNCTIONS.
- From the SPECIAL FUNCTIONS, cursor and select 9. Chemistry Update, or type 9 ENTER.

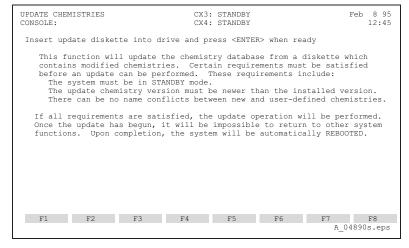


3. The main CHEMISTRY UPDATE Screen is displayed. The operator should read the requirements for a successful chemistry update as displayed on the screen. If all requirements can be met, the operator may initiate the update by pressing Y and ENTER when prompted. To exit the chemistry update function at this point, type N and ENTER at the prompt.



4. Once the operator has initiated the chemistry update, the system looks for a chemistry version file. If any errors occur at this point, a special note is displayed and the operator is prompted to press PREV SCREEN to return to the SPECIAL FUNCTIONS Screen.

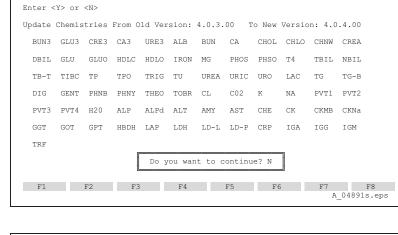
If the correct chemistry version file is located, the operator is prompted to insert a diskette and press **ENTER** to proceed.



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 The chemistries in the current version are displayed. To exit the update function at this point, type N and press ENTER.

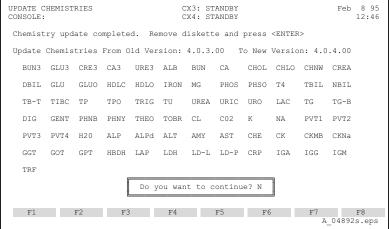
To continue with the update, the operator should type **Y** then press **ENTER**. From this point forward, the operator will not be able to exit the update.



UPDATE CHEMISTRIES

CONSOLE:

6. Messages are displayed to inform the operator of the various stages of the update process. The system begins by updating the chemistry database (adding or updating existing chemistries), then the calibrator database, the reagent database, the reagent log database, the outgas file, and finally the chemistry version file.



7. A message is displayed when the chemistry update is complete. When prompted to do so, remove the diskette and press ENTER. Wait for the system to display a prompt with further instructions.

NOTE

Ignore the error information which follows the completion of the update. This error information is an internal message, which signals the initiation of the recovery software routine.

- 8. Press **PREV SCREEN** when prompted to do so. The Shutdown Options Screen will be displayed. Select Option 2. Reboot CX Console. The system will reboot, then return the operator to the Master Screen.
- Reload calibration diskettes (Refer to paragraph 6.3.5).

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Section 7 QUALITY CONTROL

The Quality Control program provides operators with the capability of monitoring quality control and performing real-time analysis of control data. Up to 25,000 results can be stored in 500 files. QC results are stored in blocks of 30. When the QC results database reaches a status of completely full, the oldest results are overwritten in blocks of 30 to make room for incoming results. Operators are advised to consider archiving when the warning messages for 95% full, 99% full and 100% full begin to display. The QC archiving interval may vary from a few days to a month or longer, depending upon the number of controls defined, the number of chemistries per control and the frequency in which they are run. The QC files include QC log and data points for a specific chemistry/control, QC file number, assigned mean, assigned SD, constituent code, and cumulative mean, SD and N (number of data points). Control results may be archived.

Beckman Instruments recommends that at least two levels of control material should be analyzed daily. In addition, these controls should be run with each new calibration, with each new lot of reagent, and after specific maintenance or troubleshooting as detailed in the manuals. More frequent use of controls, or the use of additional controls, is left to the discretion of the user based on work load and work flow.

7.1 SELECTING HARD DISK OR FLOPPY DISK OPERATION

- 1. From the MASTER SCREEN press F5 QUALITY CONTROL.
- 2. Use the **SELECT** key to toggle the appropriate mode of operation (hard or floppy disk).

Options available from hard or floppy disk vary. These options are summarized below:

Hard Disk or Floppy Disk

- · Review demographics and statistics for an existing control file
- Produce lists of QC File numbers
- · Inform operator of hard disk space remaining
- Print QC Log, QC Summary, QC Chart and control ranges

Hard Disk Only

- · Define demographics and statistics for a new control file
- Modify existing demographics and statistics for a control file
- Clear all control files for a specified control
- · Clear a single control file
- Archive QC data to floppy disk

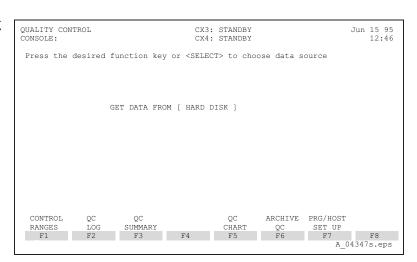
7.2 QC PROGRAMMING AND HOST SETUP

This option enables the operator to set the system to program and run quality control of CX4 side chemistries by chemistry or by reagent cartridge position. If set to program quality control by chemistry, the system selects the oldest on-board reagent cartridge when multiple cartridges of a given chemistry are residing on the system. If set to program quality control by reagent cartridge position, the operator is given the option to choose which reagent cartridges to run in a QC sample program.

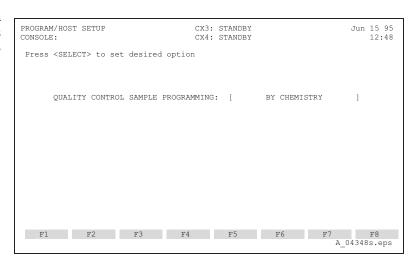
In Bar Code Mode, the system defaults to the existing sample program for that bar code identification. If no sample program exists, the system automatically runs the chemistries defined for that bar coded control as set up through F5 QUAILTY CONTROL. If the system is set to program by chemistry, the oldest on-board reagent cartridge of each defined chemistry is run. If the system is set to program by reagent cartridge position, all reagent cartridges for those chemistries are run.

If the system is set to program by reagent cartridge, the operator is also given the option to send, or not to send, Quality Control results to the host system. Some host systems may not be compatible with receiving multiple chemistry results from duplicate reagent cartridge positions. It is advisable to check with your host system representative before enabling QC Results to Host if the system is set to program QC by reagent cartridge position.

- 1. From the MASTER Screen, press F5 QUALITY CONTROL.
- From the QUALITY CONTROL Screen, press F7 PRG/HOST SET UP.



 At the field for QUALITY CONTROL SAMPLE PROGRAMMING, press SELECT to toggle between the system default, "BY CHEMISTRY" and "BY REAGENT CARTRIDGE".



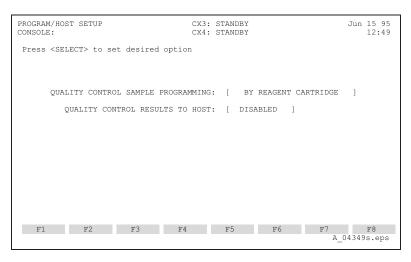
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4. At the field for QUALITY CONTROL RESULTS TO HOST, use **SELECT** to toggle between the system default, "DISABLED", and "ENABLED".

WARNING

Consult your host system representative before enabling QC Results to Host, if the system is set to program QC by reagent cartridge position. If the host system is incompatible, sending QC results to the host could result in system lockup.

5. Press **PREV SCREEN** or **MASTER SCREEN** to exit.



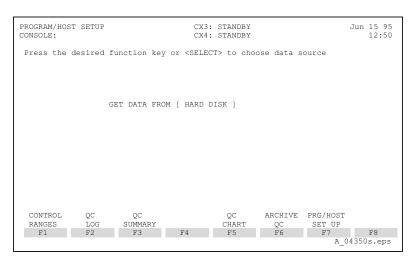
7.3 DEFINING A CONTROL

This option allows the operator to define up to 50 controls from the hard disk. The minimum input required to save a control definition is control name, lot number, QC file number, sample type and one chemistry selection. The operator can assign up to six bar codes per control (Bar Code Mode only). When a bar code control is run, the system will default to any existing sample program for that bar code. If no sample program exists, the system will automatically run the chemistries defined for that control in this section.

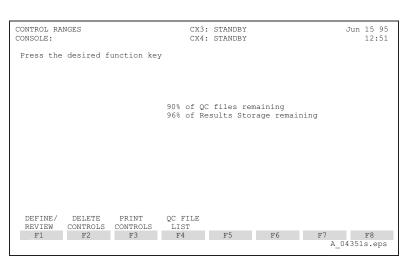
NOTE

In Bar Code Mode, when no sample program exists, the system automatically runs the chemistries defined for that bar coded control in section 7.3. Therefore, only compatible chemistries should be defined together in the same control definition. Pre-treated samples (i.e. HDLC, IBC, IgA), diluted samples or samples of different sample types should be defined as separate controls with their own bar codes.

- 1. From the MASTER SCREEN press **F5 QUALITY CONTROL**.
- From the QC MAIN Screen, make certain that the mode of operation has been set to [HARD DISK]. Use the SELECT key to toggle between modes.
- From the QC MAIN Screen press F1 CONTROL RANGES.

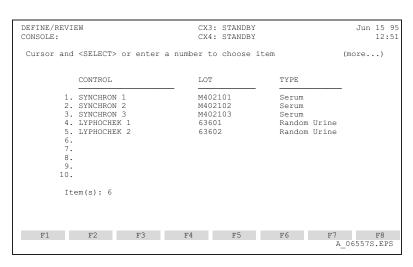


From the CONTROL RANGES Screen, press F1 DEFINE/REVIEW.

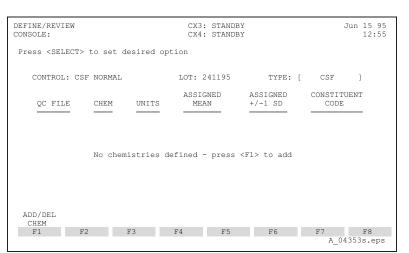


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5. Cursor and SELECT or enter the item number of the control to be defined/ edited. Use PAGE UP/PAGE DOWN to access additional control selections. If the control selected was previously defined, all current information and selected chemistries are displayed. Chemistries can be added or deleted, and mean/SD and constituent code can be modified.



- 6. Enter the control name. The control name must be unique and may be up to 20 alphanumeric characters.
- 7. Enter the control lot number (up to 12 alphanumeric characters).
- 8. Use the **SELECT** key to toggle the appropriate sample type. The default entry is [SERUM].
- Press F1 ADD/DEL CHEM to select chemistries for the control definition.

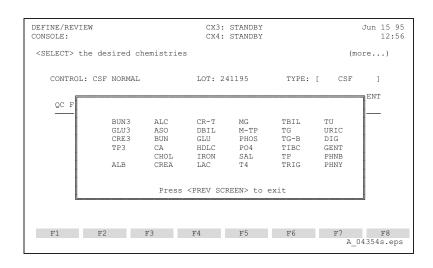


WARNING

Deselecting a chemistry from a control that has a defined QC File number, mean, SD, or constituent code DELETES the QC data and statistics for that chemistry. Archiving is suggested.

Use the **SELECT** key to select or deselect chemistries. Use PAGE **UP/DOWN** keys to access additional chemistries. When selections are complete, press **PREV SCREEN** to return to the Define/Review display.

 Press the UP/DOWN arrow keys to position the cursor on the appropriate QC File Number field.

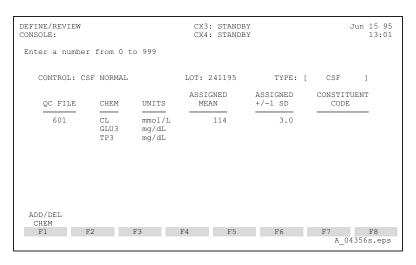


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- Enter a QC File number. This number must be a unique 3-digit number from 1 to 999. The system adds leading zeroes to numbers 1 through 99.
- 12. The cursor is active at the Assigned Mean field for the first chemistry listed. (Units displayed are those selected in System Setup, Unit Selection). Enter the assigned mean.
- DEFINE/REVIEW CX3: STANDBY CONSOLE: CX4: STANDBY 12:58 Enter a number from 1 to 999 CONTROL: CSF NORMAL LOT: 241195 TYPE: [CSF 1 ASSIGNED ASSIGNED CONSTITUENT QC FILE CHEM UNITS MEAN 601 CT. mmol/L GLU3 mq/dL TP3 mg/dL ADD/DEL F1 F2 F3 F4 F5 F6 F7 A_04355s.eps
- 13. Enter the assigned standard deviation, ±1 S.D. The system adds zeroes to the numbers depending on the precision selected in System Setup.
- 14. Enter the constituent code for the selected chemistry. Leading zeroes are added to numbers 1 through 99. Perform steps 11-14 for each chemistry. Use PAGE UP/PAGE DOWN to access additional chemistries.
- 15. Press PREV SCREEN to save the control definition and return to the DEFINE/REVIEW screen, or MAS-TER SCREEN to save definition and return to the MASTER Screen.

NOTE

For DAT chemistries, the cutoff value is printed in the control range column of the control report. The POSITIVE or NEGATIVE flag is printed in the remarks column. The operator entered control range is used for the QC Summary and Chart (Levey-Jennings) Reports.

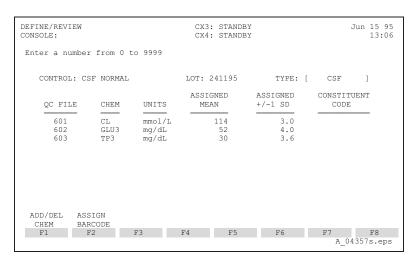


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Bar Code Assignment (Bar Code Mode Only)

Assignment of bar code IDs is mandatory for the system to "automatically" run controls without sample programming.

1. From the DEFINE/REVIEW Screen, press **F2 ASSIGN BARCODE**.



 The ASSIGN BARCODE window will display, with Control name and lot number. The cursor will be active on the first line. Type in a unique barcode ID of up to 11 alphanumeric characters. Press ENTER after each bar code entry.

WARNING

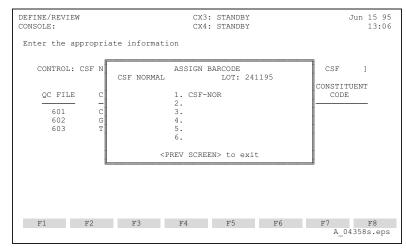
When creating Control Bar Code IDs, use a format that is distinctly different from sample IDs. This will prevent the reporting of erroneous results due to Controls being run as patient samples, or patient samples being run as Controls.

Example:

Control Bar Code ID: SYNCHRON01

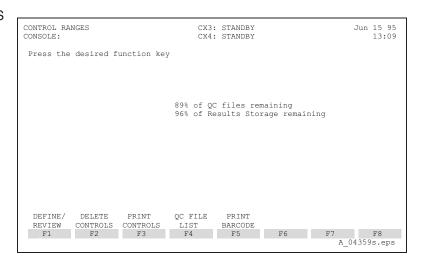
Sample Bar Code ID: 0000001

 Press PREV SCREEN to return to the DEFINE/REVIEW Screen, or MAS-TER SCREEN to exit.



Print Bar Code Assignments (Bar Code Mode Only)

1. From the CONTROL RANGES Screen, press **F5 PRINT BARCODE**.



			3 A: 11:20 PAGE	
	SYNCHRON CX	7 DELTA		
	CONTROL BARCODE	ASSIGNMENT		
CONTROL	LOT	TYPE	BARCODE	
SYNCHRON 1	M402101	Serum	SYNØØ1	
SYNCHRON 2	M402102	Serum	SYN011 SYN002 SYN022	
SYNCHRON 3	M402103	Serum	SYNØØ3 SYNØ33	
LYPHOCHEK 1	636Ø1	Random Urine	LYPHØ1	
LYPHOCHEK 2	63602	Random Urine	LYPHØ2	
CSF NORMAL	112495	CSF	CSFNORØ1	
CSF ABNORMAL	112595	CSF	CSFABNØ1	
				A_06499C.EPS

Figure 7-1. Control Bar Code Assignment List

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7.3.1 Editing a Control Definition

The assigned mean, SD, and constituent code of a previously defined control may be edited.

WARNING

Changing mean and/or standard deviation may affect subsequent QC statistical data. Archiving is suggested if mean and/or SD are changed for a control with existing data. Changing previously defined mean and/or SD to zero will set the mean to zero, and the SD to 9999.

NOTE

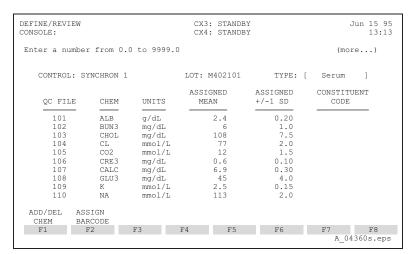
Control definitions should be edited when the system is in Standby. Data points for controls which are edited while running may not be included in Cumulative Statistics on the QC Summary.

To create a file without ranges, enter a mean of zero and an SD of 9999. All previous data will be deleted and subsequent data points will be compared to the new mean and SD.

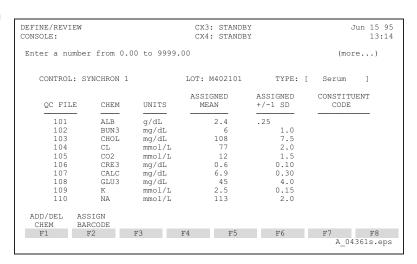
NOTE

Original accuracy and precision flags are stored with control result data and are not affected by changes to the control ranges. While the cumulative statistics are recalculated, the original accuracy and precision flags will remain.

- Refer to Section 7.2 Defining a Control, steps 1-10 to access the desired control.
- The cursor is active at the Assigned Mean field for the first chemistry listed. (Units displayed are those selected in System Setup, Unit Selection.) Enter the assigned mean.



Enter the assigned standard deviation (1 S.D.).

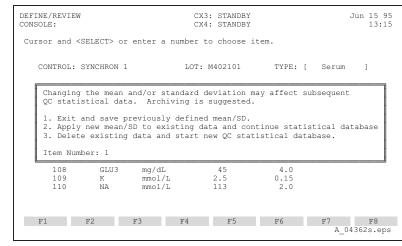


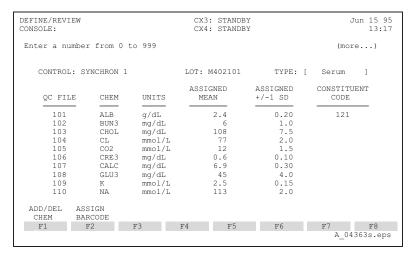
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- 4. A change to a non-zero mean and/or SD may affect subsequent QC statistical data. A pop-up window prompts the operator to designate how the changes will be applied to subsequent data:
 - (a) Exit and save previously defined mean/SD.
 - (b) Apply new mean/SD to existing data and continue the statistical database.
 - (c) Delete the existing data and start a new QC statistical database.

Cursor and **SELECT** the appropriate action, or enter the item number of the desired action and press **ENTER**.

- If a change was made to mean and/or SD, the change is reflected in the Define/Review display. If changes were not saved, the previously defined mean/SD are displayed.
- If desired, enter the new constituent code. Use ARROW keys and PAGE UP/PAGE DOWN to access additional chemistries. Press PREV SCREEN to return to the DEFINE/ REVIEW Control selection display.
- To edit Bar Code ID assignments (Bar Code Mode only), press F2 ASSIGN BARCODE from the DEFINE/ REVIEW Screen.





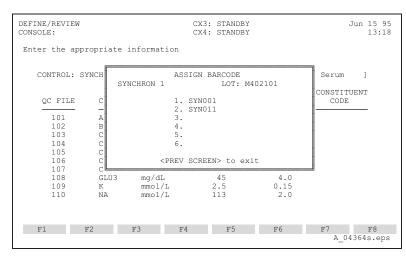
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8. Move the cursor to the appropriate line and type in new ID and press **ENTER**. Press **PREV SCREEN** to return to the DEFINE REVIEW Screen.

NOTE

The operator must clear out any existing sample programs with the old Bar Code ID and program new control sample programs with the new Bar Code ID, if applicable.

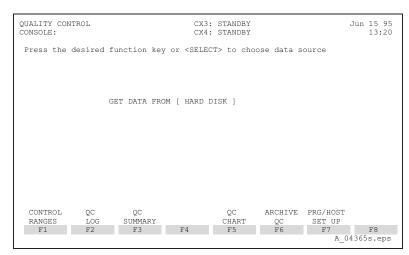
 Press PREV SCREEN to return to the CONTROL RANGES Screen, or press MASTER SCREEN to return to the MASTER Screen.



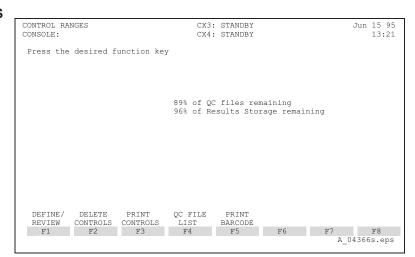
7.3.2 Reviewing a Control Definition

A control definition can be reviewed from either hard disk or floppy disk operation. From the Floppy Disk, no modifications to the control file are allowed.

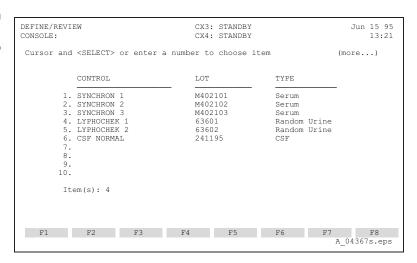
- From the MASTER Screen press F5 QUALITY CONTROL.
- From the QC MAIN Screen, use SELECT to set the mode to Hard Disk or Floppy Disk.
- 3. From the QC MAIN screen, press **F1 CONTROL RANGES**.



4. From the **CONTROL RANGES** Screen, press **F1 DEFINE/REVIEW**.

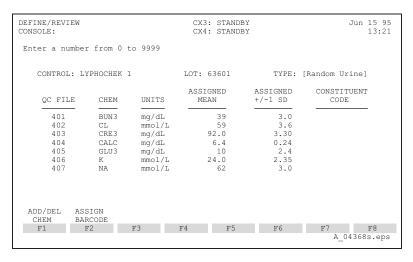


 Cursor and SELECT or enter the item number of the control to be reviewed.
 Use PAGE UP/PAGE DOWN to access additional control selections.



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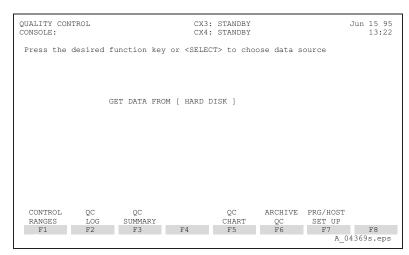
- All current information and selected chemistries are displayed. If using a Floppy Disk, no cursor will be available because changes are not allowed.
- Press PREV SCREEN to return to the Define/Review Display. SELECT another control to review or press MASTER SCREEN to exit.



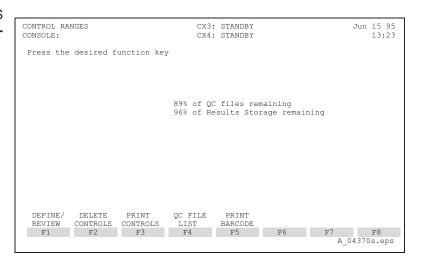
7.3.3 Deleting a Control

This option allows the operator to remove a previously defined control from the system. Clearing QC ranges must be done in the Hard Disk mode.

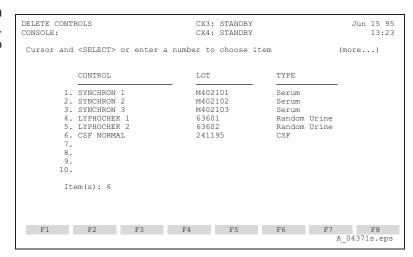
- From the MASTER Screen press F5 QUALITY CONTROL.
- In the QC MAIN Screen make certain that the mode is set to [HARD DISK]. Use the SELECT key to toggle between modes.
- From the QC MAIN Screen, press F1 CONTROL RANGES.



 From the CONTROL RANGES Screen, press F2 DELETE CON-TROLS.

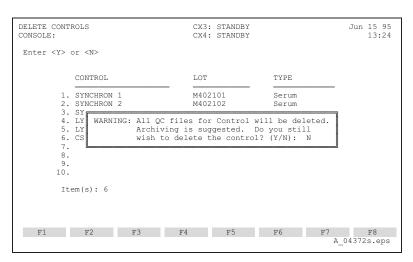


 Cursor and SELECT or enter the item number of the control to be cleared.
 Use PAGE UP/PAGE DOWN to access additional controls.

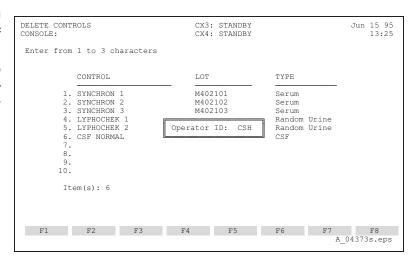


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6. To confirm the clearing of the selected control, enter Y. All statistical data as well as the control name, lot number, file number, sample type and selected chemistries are deleted from the database. If you do not wish to delete the control, enter N; the control will remain as defined on the system.



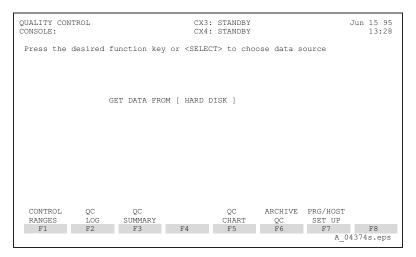
- 7. If **Y** was selected in Step 6, enter an operator ID of 1 to 3 alphanumeric characters at the prompt.
- Press PREV SCREEN to return to the CONTROL RANGES Screen or MAS-TER SCREEN to return to the MAS-TER Screen.



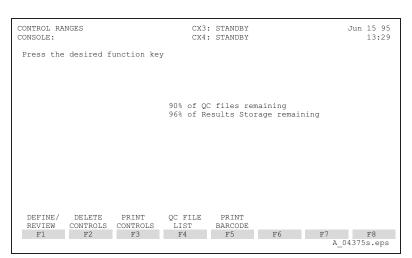
7.4 PRINTING QC RANGES

This option is used to print the entire database of controls, and is accessible from either the hard disk or from the floppy disk.

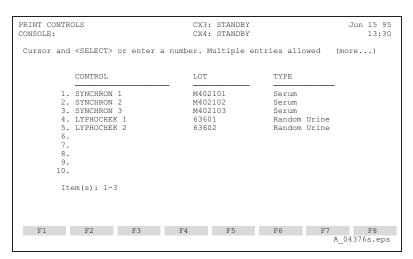
- From the MASTER Screen press F5
 QUALITY CONTROL.
- From the QC MAIN Screen press F1 CONTROL RANGES.



3. From the CONTROL RANGES Screen press **F3 PRINT CONTROLS**.



- Cursor and SELECT the control to be printed, or enter the item number. Use PAGE UP/PAGE DOWN to access additional controls. Multiple entries are allowed.
- 5. Pressing **ENTER** initiates the printing of control ranges. (For an example of the report, see Appendix F).
- To print additional ranges, repeat steps 4 through 5. Press PREV SCREEN to return to the CONTROL RANGES Screen or MASTER SCREEN to return to the MASTER Screen.

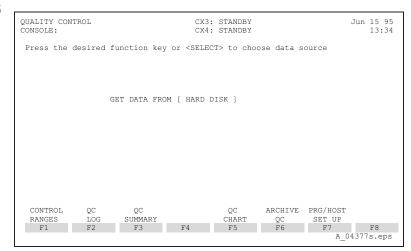


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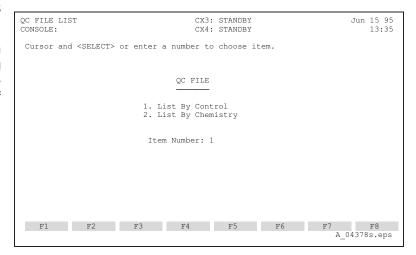
7.5 QC FILE LIST

QC File List allows the operator to view and/or print a list of QC files by control or chemistry. QC File List is accessible from either Hard Disk or Floppy Disk.

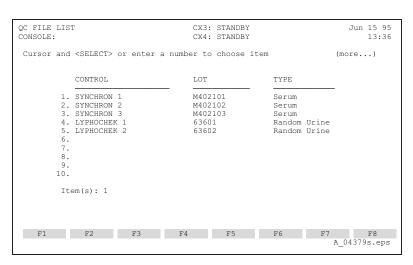
- 1. From the MASTER Screen press **F5 QUALITY CONTROL**.
- From the QC MAIN Screen press F1 CONTROL RANGES.



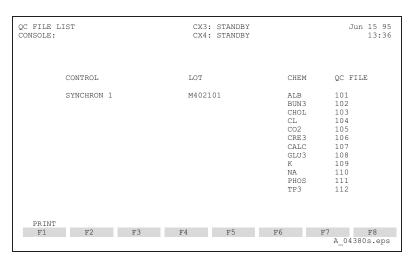
- 3. From the CONTROL RANGES Screen, press **F4 QC FILE LIST**.
- Cursor and SELECT or enter the item number of the QC File List grouping desired. If item 1. QC File List by Control is selected, continue with step 5. If QC File List by Chemistry is selected, proceed to step 7.



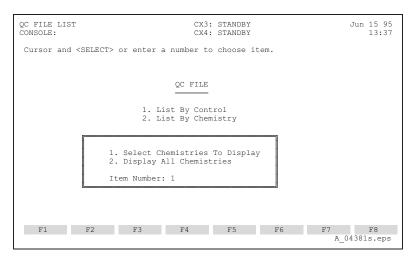
 The list of currently defined controls is displayed. Use PAGE UP/PAGE DOWN to access additional controls. Cursor and SELECT or enter the item number of the control desired.



 The QC File list is displayed with the chemistries in alphabetical order. Use PAGE UP/PAGE DOWN to view additional chemistries. Press F1 PRINT to print the QC File list.



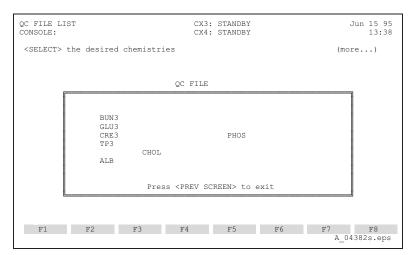
7. If QC File List by Chemistry is selected, a pop-up window prompts the operator to designate whether only selected chemistries or all chemistries are to be listed.



(a) To list selected chemistries, cursor and SELECT 1. Select Chemistries to Display or type 1 ENTER. A pop-up window displays the chemistries currently defined for controls.

Use the SELECT key to designate the chemistries desired in the list. Use PAGE UP/PAGE DOWN to access additional chemistries. When selections are complete, press PREV SCREEN. The QC File List is displayed; additional chemistries are accessed with PAGE UP/PAGE DOWN.

Press **F1 PRIN**T to initiate printing.

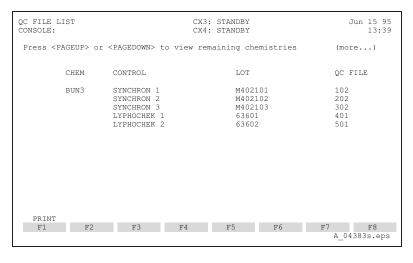


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(b) To list all chemistries, cursor and **SELECT 2**. Display all Chemistries, or type **2 ENTER**.

Chemistries are listed in alphabetical order, with controls in ascending order. Use **PAGE UP/PAGE DOWN** to access additional chemistries.

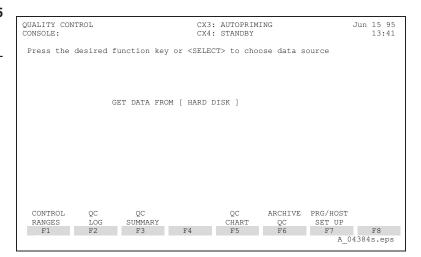
Press **F1 PRINT** to initiate printing.



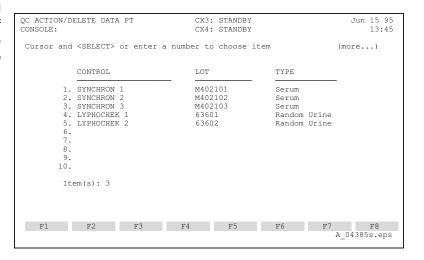
7.6 QC LOG

The QC Log displays results with information about the relationship of those results to the assigned mean, SD and previous results for a specified data interval. Also displayed are data point deletions and information entered by the operator through the QC Action Log /Deletion function. The QC Action Log/Deletion function is accessed through QC Log. The QC Log may be viewed and/or printed from either the hard disk or the floppy disk. Data points may be deleted at the operator's discretion from the hard disk only. When printing, the system must be in Standby due to the possible length of the report.

- From the MASTER Screen, press F5 QUALITY CONTROL.
- From the QUALITY CONTROL screen, press F2 QC LOG.

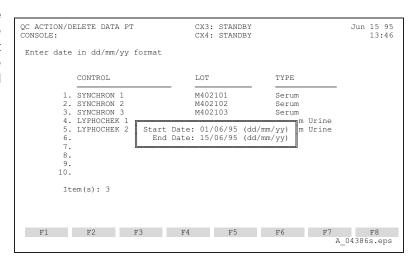


 Cursor and SELECT the control desired, or type the item number of the control and press ENTER. Use PAGE UP/PAGE DOWN keys to access additional controls.



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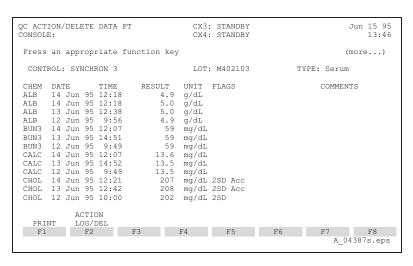
4. Enter a start date and an end date using the dd/mm/yy format. The default start/end date is the current date. Press ENTER to select the default, or after entering the start and end dates.



5. The QC Log is displayed in alphabetical order by chemistry, with most recent data entries first. Also displayed are the date, time run, result, units, relationship of the result to the assigned mean and previous results, and action log comments. Use PAGE UP/PAGE DOWN keys to access additional data.

Data points > 2SD are displayed in yellow. Data Points > 3SD are displayed in red. Data points > 2SD with Precision or Accuracy flags are displayed in red. For a description of how Accuracy and Precision are determined refer to Appendix F.

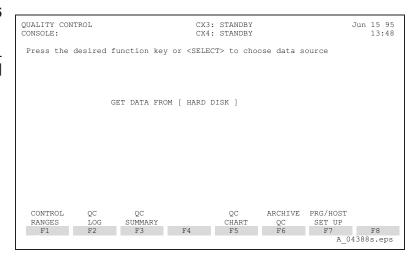
- 6. Press **F1 PRIN**T to initiate printing of the log.
- Press PREV SCREEN to return to the QUALITY CONTROL Screen, or MASTER SCREEN to return to the MASTER Screen.



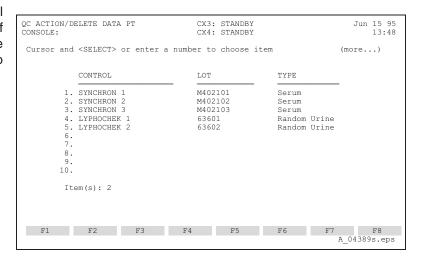
7.6.1 Action Log Entry and Deleting a Data Point

This option allows the operator to attach comments to data points and/or delete data points. Deleting a data point removes the data point from the database and adjusts the QC statistics. The data point is not deleted from the QC Log. Archiving is suggested before deletions are made. This function is only available from the hard disk.

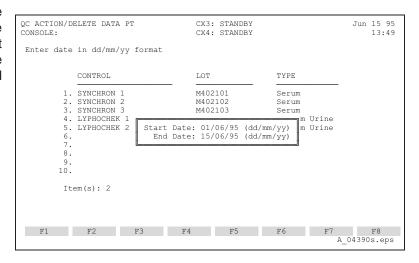
- From the MASTER Screen, press F5 QUALITY CONTROL.
- From the QUALITY CONTROL Screen, SELECT the [HARD DISK] mode, then press F2 QC LOG.



 Cursor and SELECT the control desired, or type the item number of the control and press ENTER. Use PAGE UP/PAGE DOWN keys to access additional controls.



4. Enter a start date and an end date using the dd/mm/yy format. The default start/end date is the current date. Press ENTER to confirm the default, or after entering the start and end dates.



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The QC Log for the control selected is displayed. From the QC Log Screen, press F2 ACTION LOG/DEL.

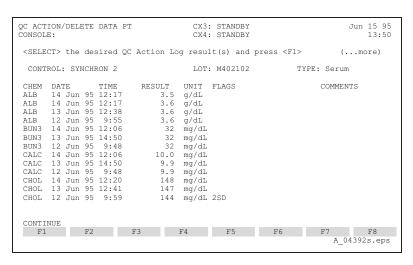
QC ACT	ION.	/DELI	ETE	DATA P	Т	CX3	: STANDBY		Jun 15 95
CONSOL	E:					CX4	: STANDBY		13:49
Press	an	appi	rop	riate f	unction key	7			(more)
			1-						(
CONT	ROL	: SY	(CH	RON 2		LOT	: M402102	TY	PE: Serum
CHEM	DA'	ΓE		TIME	RESULT	UNIT	FLAGS		COMMENTS
ALB	14	Jun	95	12:17	3.5	g/dL			
ALB	14	Jun	95	12:17	3.6	g/dL			
ALB	13	Jun	95	12:38	3.6	g/dL			
ALB	12	Jun	95	9:55	3.6	g/dL			
BUN3	14	Jun	95	12:06	32	mg/dL			
BUN3	13	Jun	95	14:50	32	mg/dL			
BUN3	12	Jun	95	9:48	32	mg/dL			
CALC	14	Jun	95	12:06	10.0	mg/dL			
CALC	13	Jun	95	14:50	9.9	mg/dL			
CALC	12	Jun	95	9:48	9.9	mg/dL			
CHOL	14	Jun	95	12:20	148	mg/dL			
CHOL	13	Jun	95	12:41	147	mg/dL			
CHOL	12	Jun	95	9:59	144	mg/dL	2SD		
		A	TT	ON					
PRT	NT)G/I						
F1			F2		F3	F4	F5	F6	F7 F8
									A 04391s.eps

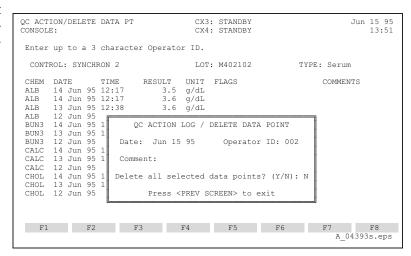
6. Cursor and SELECT the data points desired. Use PAGE UP/PAGE DOWN keys to access additional data. Multiple selections are allowed so the operator can apply the same comments to, and/or delete the data points selected. When data point selection is complete, press F1 CONTINUE to open the QC ACTION LOG/DELETE DATA POINT window.

NOTE

If data points already have action log comments and/or deletions associated with them, the system will only allow the operator to select those data points with identical comments and deletion status for selection at the same time.

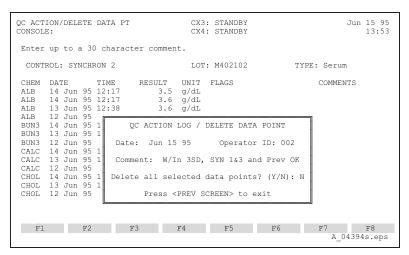
 The current data will be displayed. At the operator ID prompt, enter an operator ID of 1 to 3 alphanumeric characters.





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- 8. At the comment prompt, enter a comment of 1 to 30 alphanumeric characters (optional).
- Type Y or N at the "Delete all selected data points?" prompt. The default is N.



 To confirm deletion of the data point(s), enter Y. To discontinue deletion, enter N.

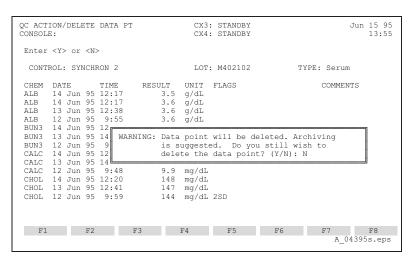
NOTE

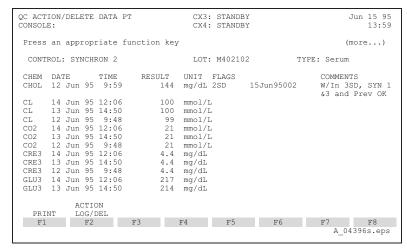
The "@" symbol is used to indicate that the information in the field is too long for the allotted field length. This occurs when a control data point is deleted. The results recall screen for that control will display the "@" symbol in the remarks column instead of "QC RESULT DELETED."

 The updated QC Log will display comments and deletion status, if applicable, along with the date of the entry and operator ID.

Press **F1 PRINT** to initiate printing of the Log.

 Press PREV SCREEN to return to the QUALITY CONTROL Screen, or MASTER SCREEN to return to the MASTER Screen.





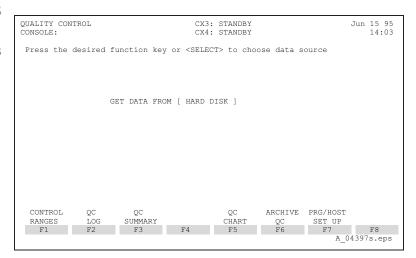
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7.7 QC SUMMARY

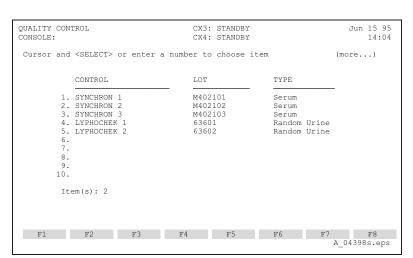
The QC Summary report contains the mean, SD, CV and number of results (N) for any control run within a specified date interval. The printed report contains the cumulative mean, SD, CV and (N)umber of accumulated results.

The QC Summary is also available in the CAP format.

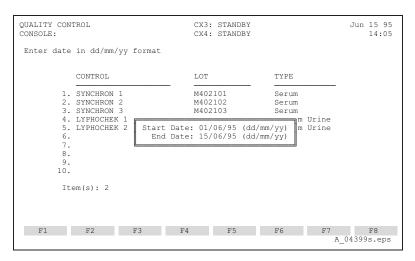
- From the MASTER Screen, press F5 QUALITY CONTROL.
- From the QC MAIN Screen, press F3 QC SUMMARY.



A list of currently defined controls is displayed. Cursor and SELECT the control for the QC Summary, or type the item number and press ENTER.



4. Enter a start date and an end date using the dd/mm/yy format. The default start/end date is the current date. Press ENTER to select the default, or after entering the start and end dates.



5. The QC Summary for the specified date interval is displayed. To print a hard copy of the summary, press **F1 PRINT** (to print the CAP format of the QC Summary, refer to Paragraph 7.7.1, step 5).

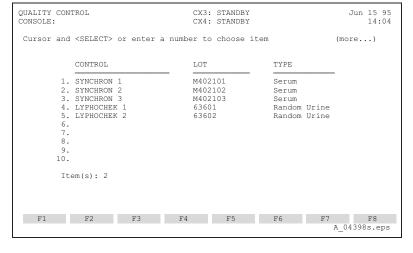
QUALITY CONTROL CONSOLE:		B: STAN				Jun 1	5 95 4:06		
Press an appropriate	function	key					(more.)	
CONTROL: SYNCHRON 2		LOT: M402102				TYPE: Seru	ım		
START DATE:	1 Jun	95	END	DATE:	15	Jun 95			
		SUMMARY				CUMULATIVE	SUMMARY		
ASSIGNED									
CHEM MEAN SD	N	MEAN	SD	CV	N	MEAN	SD	CV	
ALB 3.7 0.20	4	3.58	0.05	1.4	4	3.58	0.05	1.4	
BUN3 33 2.0	3	32.0	0.0	0.0	3	32.0	0.0	0.0	
CHOL 167 10.0	3	146.3	2.1	1.4	3	146.3	2.1	1.4	
CL 100 2.5	3	99.7	0.6	0.6	3	99.7	0.6	0.6	
CO2 21 1.5	3	21.0	0.0	0.0	3	21.0	0.0	0.0	
CRE3 4.4 0.20	3	4.40	0.00	0.0	3	4.40	0.00	0.0	
CALC 9.9 0.40	3	9.93	0.06	0.6	3	9.93	0.06	0.6	
GLU3 221 7.0		215.0	1.7	0.8	3	215.0	1.7	0.8	
K 5.1 0.15	3	5.10	0.00	0.0	3	5.10	0.00	0.0	
937									
CAP PRINT PRINT									
F1 F2	F3	F4	F5		F6	F7	F	'8	
			- 20				04400s		

 Press PREV SCREEN to return to the QUALITY CONTROL Screen, or press MASTER SCREEN to return to the MASTER Screen.

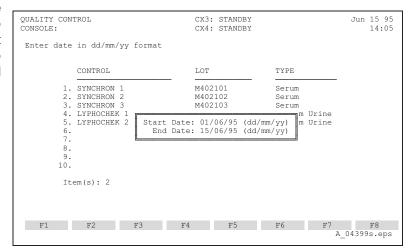
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7.7.1 QC Summary - CAP Format

- From the MASTER Screen, press F5 QUALITY CONTROL.
- From the QC MAIN Screen, press F3 QC SUMMARY.
- A list of currently defined controls is displayed. Cursor and SELECT the control for the QC Summary, or type the item number and press ENTER.



4. Enter a start date and an end date using the dd/mm/yy format. The default start/end date is the current date. Press ENTER to select the default, or after entering the start and end dates.



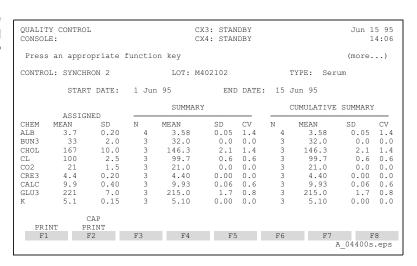
The QC Summary is displayed for the specified date interval. To print a hard copy of the summary, press F2 CAP PRINT.

NOTE

Constituent code must be defined in order for a chemistry to be included in the CAP QC Summary.

To enter CAP reference number and contact person to be included in CAP QC Summary access Report Setup through System Setup.

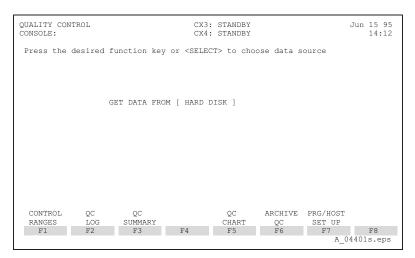
 Press PREV SCREEN to return to the main QC Screen, or press MASTER SCREEN to return to the MASTER Screen.



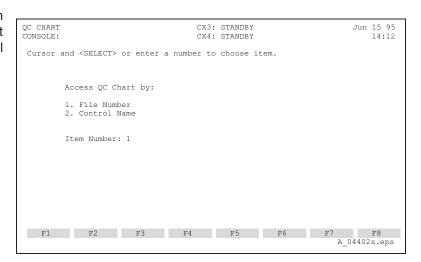
7.8 QC CHART (Levey-Jennings)

The QC Chart displays the results in a control for a specified period (default is current date) in a graphic form, showing the position of data points relative to the assigned mean and standard deviation. The results are listed by date and time, most recent results first. QC Chart is available from either the hard disk or the floppy disk.

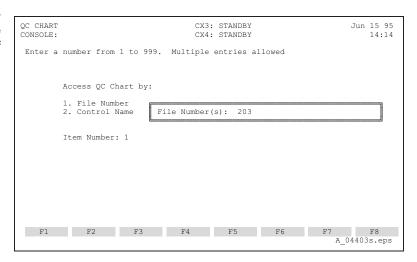
- From the MASTER Screen press F5 QUALITY CONTROL.
- From the QC MAIN Screen, press F5 QC CHART.



 Cursor and SELECT or enter the item number for the desired chart format (1. QC File number or 2. Control name).

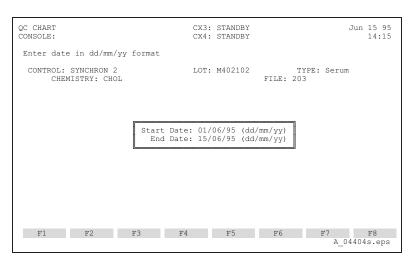


4. If QC Chart is accessed by file number, enter the file number at the prompt; multiple entries are allowed. If accessing QC Chart by control name, proceed to step 7.



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 The control name, lot number, sample type and chemistry name for the first file are displayed. Enter a start and end date in dd/mm/yy format, and press ENTER. To select the current date press ENTER.

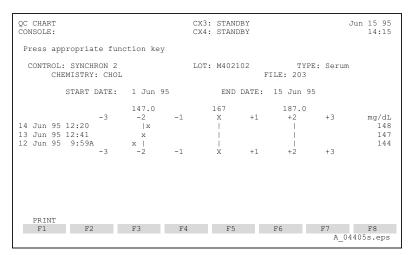


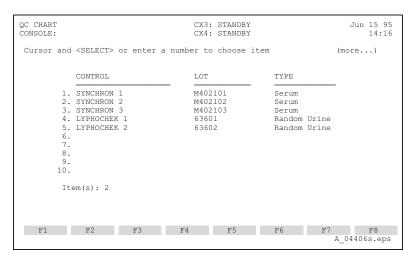
6. The QC Chart is displayed. Use PAGE UP/PAGE DOWN to view additional data. If no data exists for the dates entered, the message "No Data Available" is displayed. Press F1 PRINT to print a copy of the QC Chart.

NOTE

An "A" next to the time indicates that an action log entry exists for the data point.

If QC Chart is to be accessed by control, the currently defined controls are displayed. Use PAGE UP/PAGE DOWN to access additional controls. Cursor and SELECT or enter the item number of the desired control.



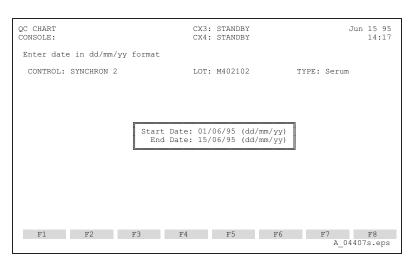


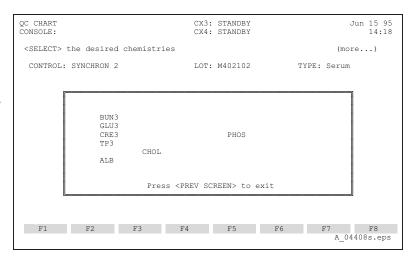
 Enter a start and end date for the QC Chart in the dd/mm/yy format or press ENTER to default to the current date. If no data exists for the dates entered, the message "No Data Available" is displayed.

NOTE

User defined chemistries which have been cleared cannot be retrieved for QC Chart.

- 9. The chemistries defined for the selected control are displayed. Upon display, all chemistries appear selected. Cursor and press SELECT to de-select any chemistries which should not be charted. Multiple selections are allowed. Use PAGE UP/PAGE DOWN to access additional chemistries. When selections are complete press PREV SCREEN to display the QC Chart(s).
- 10. Press F1 PRINT to print. Press PREV SCREEN to return to the QUALITY CONTROL Screen, or MASTER SCREEN to return to the MASTER Screen.



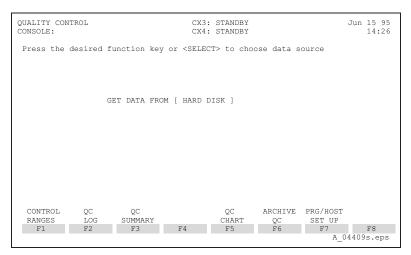


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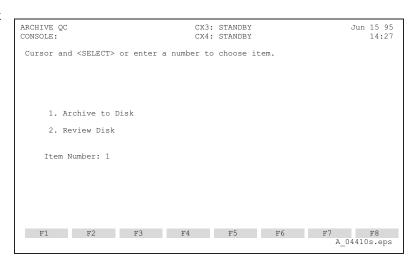
7.9 ARCHIVE QC

The Archive QC function archives control definition (control name, lot number, sample type, QC File number, QC Log selected chemistries, assigned mean and SD, constituent code, and cumulative mean, SD and N) and results to a floppy disk. Archiving is available from the hard disk only. The archived floppy disk can be used to review data, but not to modify QC files. The system must be in standby to archive QC data.

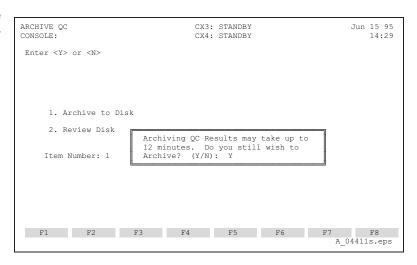
- From MASTER Screen, press F5 QUALITY CONTROL.
- From the QC MAIN Screen, use the SELECT key to toggle mode to [HARD DISK].
- From the QC MAIN Screen press F6 ARCHIVE QC.



4. Cursor and **SELECT** Archive to Disk or type **1 ENTER**.



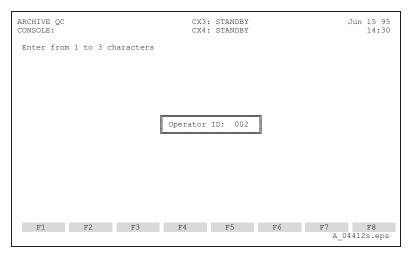
To confirm the continuation of the archive process, enter Y. To discontinue process, enter N.



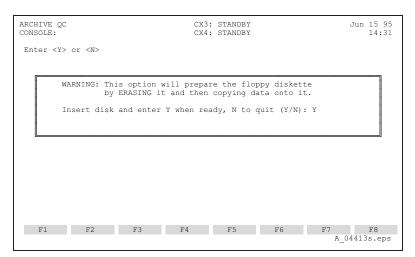
6. Enter an operator ID of 1 to 3 alphanumeric characters.

NOTE

Diskette must be double sided, high density.



Insert a disk and type Y at the prompt when ready. The disk will be formatted by erasure, then the QC data will be archived to it.



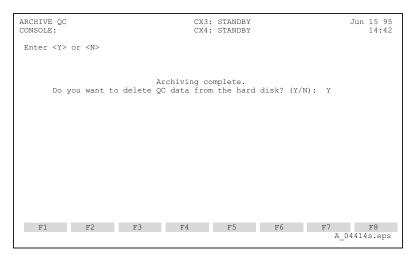
8. When archiving is complete, a prompt will ask the operator if QC data should be deleted from the hard disk.

WARNING

Once QC data is deleted from the hard disk, no modifications are allowed.

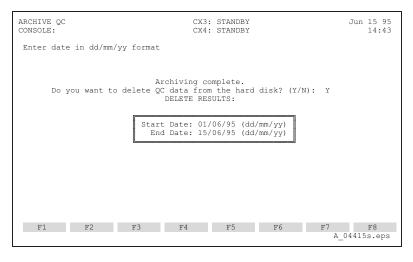
If the operator answers Y to the delete QC data prompt, a warning is displayed. Press ENTER to initiate deletion.

Cumulative statistics are not affected by this deletion.



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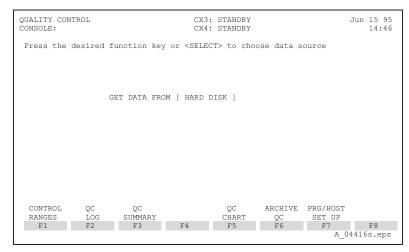
- Select a date interval for QC data deletion by entering a start date and an end date using the dd/mm/yy format.
- 10. When deletions are complete, press PREV SCREEN to return to the QC MAIN Screen, or MASTER SCREEN to return to MASTER Screen.



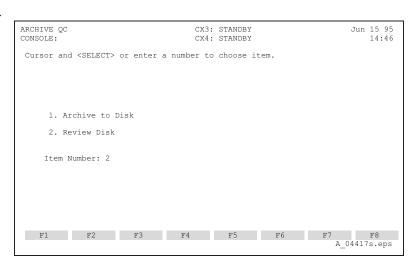
7.9.1 Reviewing Archived Data

Archived data can be reviewed from a floppy disk. Review options available from the floppy include review of demographics and cumulative statistics for a control file, display and printing of QC File List, QC Log, QC Summary and Control Ranges. No modifications to the archived control files are allowed.

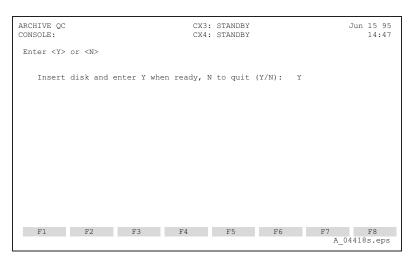
- From the MASTER Screen, press F5 QUALITY CONTROL.
- From the QC MAIN Screen, use the SELECT key to toggle the mode to [HARD DISK].
- 3. Press F6 ARCHIVE QC.



Cursor and SELECT Review Disk, or type 2 ENTER.



5. Insert the archive disk and type **Y** at the prompt.

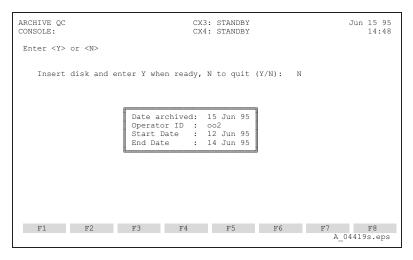


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6. Information about the archive disk (date archived, operator ID, start date, end date) is displayed. If the information indicates that the proper disk has been entered, press N to cancel the disk review process and return to the Archive menu screen. Press PREV SCREEN to return to the main QC Screen. Continue with Step 7.

If the information indicates that this is not the proper diskette, press **Y** and insert the next diskette; review the information displayed and press **Y** or **N** accordingly as described above.

- From the main Quality Control Screen, use the SELECT key to toggle the mode to [FLOPPY DISK].
- Floppy disk retrieval provides access to data review of Control Ranges, QC Log, QC Summary and QC Chart. No modification to the data is allowed.
- Press F1 CONTROL RANGES. From the CONTROL RANGES Screen, the following selections can be made:
 - F1 DEFINE/REVIEW to review control definition and function keys to display and print QC charts, QC logs, and QC summaries.
 - F4 QC FILE LIST to display and print QC File lists.
 - F3 PRINT CONTROLS to print control ranges.



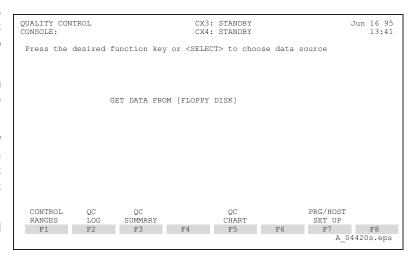


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8.1 INTRODUCTION

The user may define up to 100 chemistries on the SYNCHRON CX4 Systems by defining a set of parameters which will fully characterize an analyte of interest. Once defined, the parameters described in Table 8-1 are stored in memory according to the test name designated in setup. These chemistries can then be configured on the test selection menu for programming along with the Beckman-defined chemistries.

8.1.1 User-Defined Reagent (UDR) Cartridges

The appropriate one-, two-, or three-component reagent is placed in user-defined, three-compartment cartridges which can then be loaded on the system manually (Figure 8-1). The label on the cartridge should be marked with the reagent name (Figure 8-2). The maximum and minimum fill volumes required to allow for accurate level sensing are as follows:

	Compartment A	Compartment B	Compartment C
Maximum Fill Volume	110 mL	18 mL	4 mL
Minimum Fill Volume	6 mL	1 mL	User-Defined Reagent Cartridge



Figure 8-1. User-Defined Reagent Cartridge Label

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Figure 8-2. User-Defined Reagent Cartridge Label

NOTE

Since Beckman does not manufacture or otherwise control the reagents that our Customers may use in these user-defined cartridges, Beckman makes no warranty whatsoever with respect to such reagent's performance (including test results), their effect on the system, required system maintenance or the frequency thereof, or their effect on operator safety. User assumes full responsibility for use of the proper test protocol and test result generation for the reagent or reagents selected by the user and for any errors or omissions associated therewith. BECKMAN EXPRESSLY DISCLAIMS ALL WARRANTIES WITH RESPECT TO THIS PRODUCT WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

CAUTION

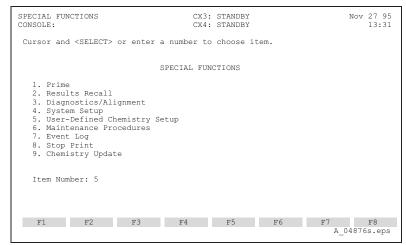
Non-Beckman reagents, calibrators, and controls can contain components, not listed on the insert, which may carryover in the system causing chemical or spectral interference. This carryover could adversely affect results on an otherwise well performing system. Manufacturers of UDR reagents should be contacted for disclosure of potentially interfering substances, such as preservatives.

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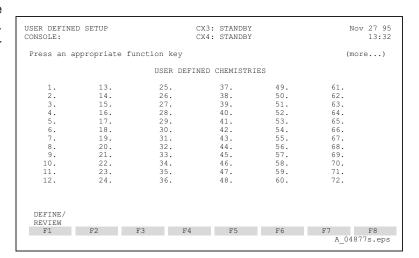
8.2 USER-DEFINED CHEMISTRY SETUP

8.2.1 Defining a Chemistry

- From the MASTER Screen, press F4 SPECIAL FUNCTION.
- Cursor and SELECT 5. User Defined Chemistry Setup or type 5 ENTER.



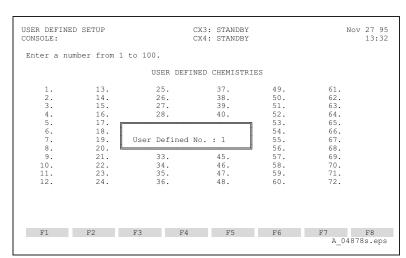
 Listed are 72 out of 100 available positions for user-defined chemistries.
 Press PAGE DOWN to view additional positions.



4. Press **F1 DEFINE/REVIEW**. Type the position number and press **ENTER**.

NOTE

Parameters for a user-defined chemistry may not be edited while the reagent is loaded on the reagent carousel, or if pending tests exist.



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 Starting with the Test Name, define all of the appropriate parameters applicable to the chemistry being characterized. (Refer to Table 8-1 for setup parameter descriptions.)

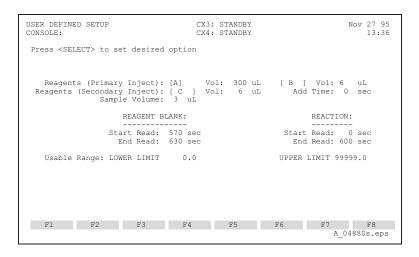
NOTE

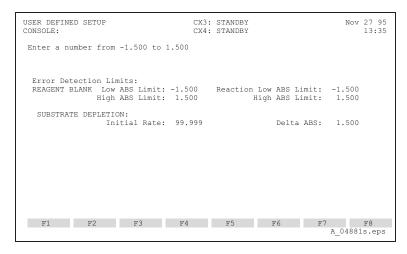
It is necessary to make an entry in the Test Name field before exiting the screen. If the screen was entered inadvertently, type an entry for the Test Name field and press **PREV SCREEN**, then **Y**. At the USER DEFINED SETUP Screen clear the test name using **F2 CLEAR CHEMISTRY**.

Use the cursor control keys or press **ENTER** to access the various fields. Fields enclosed by brackets ([]) may contain two or more options that are toggled by pressing **SELECT**. The remaining fields require typed-in entries.

Press **PAGE DOWN** to enter each successive page. There are three screens associated with setup.

DBY Nov 27 95 DBY 13:36
(more)
ETERS
User defined No. 1 No. of Calibrators:[0] Calibrator 1: 0.00 2: 0.00 3: 0.00 4: 0.00 5: 0.00 6: 0.00 Cal Time Limit: 0 hr
F6 F7 F8 A 04879s.eps





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6. Multipoint span values are displayed only for the number of calibrators specified on the first data screen. A change in number of calibrators resets the span values to zero for reentry by the operator. Recovery and sensitivity fields are displayed only for chemistries with 5 or more calibrators.

When the last screen has been completed, press **PREV SCREEN** to exit to the USER DEFINED CHEMISTRIES Screen or press **MASTER SCREEN** to exit to the MASTER Screen.

NOTE

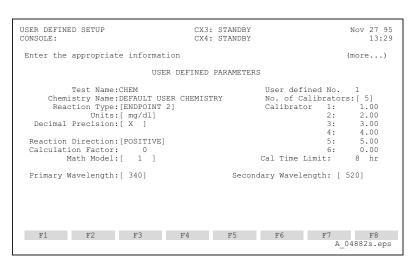
Upon exiting any of the screens, the defined parameters are validated for completeness and appropriate input. If any discrepancy exists, the user is informed which parameter(s) MUST be corrected before the test can be run.

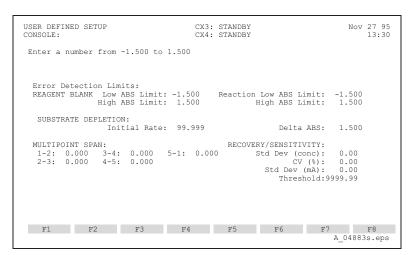
- 7. To obtain a hard copy of the parameters, press **F3 PRINT**.
- 8. Type the position number of the chemistry to be printed and press **ENTER**.
- The newly defined test must be configured on the chemistry menu in order to program samples and load reagent.

To reach the CHEMISTRY CONFIGURATION Screen, press PREV SCREEN to return to the SPECIAL **FUNCTIONS** Screen. Select 4. SYSTEM SETUP, then 1. Configure Chemistry Menu. The menu is divided into two pages of 36 chemistries each. Move cursor to the desired position on the menu and enter the chemistry name exactly as defined under the Test Name parameter.

To obtain a printout of all the Defined Chemistries, press **F1 LIST ABBREV**.

 Press PREV SCREEN to return to the SYSTEM SETUP Screen or press MASTER SCREEN to exit.





USER DEFINED SETUP CONSOLE:		3: STANDBY 4: STANDBY		No	ov 27 95 13:30
Press an appropriate fur	ction key			(mc	re)
	USER DEFINE	D CHEMISTRIES	3		
1. CHEM 13. 2. 14. 3. 15. 4. 16. 5. 17. 6. 18. 7. 19. 8. 20. 9. 21. 10. 22. 11. 23. 12. 24.	25. 26. 27. 28. 29. 30. 31. 32. 33. 34. 35.	37. 38. 39. 40. 41. 42. 43. 44. 45. 46. 47.	49. 50. 51. 52. 53. 54. 55. 56. 57. 58. 60.	61. 62. 63. 64. 65. 66. 67. 68. 69. 70. 71.	
	INT 3 F4	F5	F6	F7	F8 84s.eps

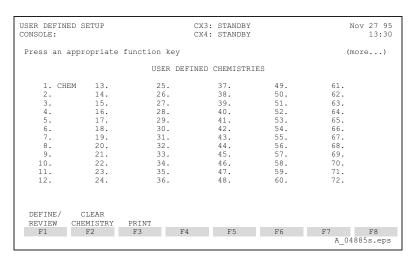
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8.2.2 Clearing a User-Defined Chemistry

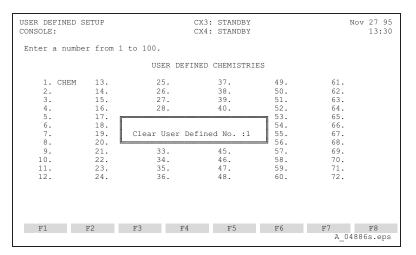
NOTE

Clearing a User-defined chemistry deletes all references to the QC File number, deletes associated reference ranges, and deletes associated patient results and QC results. This process may take up to six minutes. User-defined chemistries with pending tests cannot be cleared.

 From the USER DEFINED SETUP Screen, page to the screen listing the chemistry to be cleared and press F2 CLEAR CHEMISTRY.



- At the prompt, type the position number of the chemistry to be cleared and press ENTER.
- A warning window appears advising the operator that Host Communications will be disabled while the database is being updated.
- At the confirmatory prompt, type Y to continue with the UDR deletion/database update. Type N if you do not wish to clear the test.
- Press PREV SCREEN or MASTER SCREEN to exit to the MASTER Screen.



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8.3 SETUP PARAMETERS

Table 8-1 lists and describes the setup parameters required for a user-defined chemistry.

Table 8-1. User-Defined Chemistry Setup Parameters

TEST NAME

Allowable Entry: A maximum of four alpha-numeric characters.

The name cannot begin with a numeric entry or be the same as an existing Beckman chemistry test name or calculation name. Duplicate test names cannot be used by entry in upper vs. lower case letters; test name is stored and retrieved in upper case letters only. The designated test name is used as the chemistry code described in Host Computer Interface Specifications, Section Ten.

REACTION TYPE

Options: Endpoint 1 Reagent blank is not subtracted.

Endpoint 2 Reagent blank is subtracted.
Rate 1 Reagent blank is not subtracted.
Rate 2 Reagent blank is subtracted.

(Refer to Spectrophotometric Principles of Measurement, Paragraph 4.4, for a detailed explanation of each type.)

UNITS

Options: mg/dL IU/L mA

mg/L μg/mL mA/min g/dL Rate ng/mL g/L mmol/L ng/dL mmol/L μg/dL μIU/mL μmol/L μg/L mIU/mL mEq/L U/L IU/mL Ku/u U/mL μKat/L

nKat/L %

Other

WARNING

Changing previously defined units for a UDR chemistry is not allowed if the UDR is included in a current control definition. In addition, changing units will invalidate recalled results and delete associated reference ranges.

DECIMAL PRECISION

Options: X

X.X X.XX

Specifies the number of decimal places for reporting results.

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Table 8-1. User-Defined Chemistry Setup Parameters (Continued)

REACTION DIRECTION

Options: Positive Increasing absorbance Negative Decreasing absorbance

CALCULATION FACTOR

Allowable Range: 0 to 99999

Value must be entered if no calibrators are defined. Additional slope and offset adjustments may be made at the CALIBRATION Screen (Paragraph 6.3).

For calculating the appropriate factor for rate chemistries, a derivation of the Beer's Law formula as applied to bichromatic chemistries can be used as follows:

$$\frac{\text{Delta ABS/min}}{\text{e}^{1}-\text{e}^{2}} \times \frac{\text{T.V.}}{\text{S.V.}} \times \frac{1000}{0.5}$$

where:

Delta ABS/min = The delta absorbance/minute obtained bichromatically.

e¹ = The extinction coefficient of the chromophore at the primary wavelength.

e² = The extinction coefficient of the chromophore at the secondary wavelength.

NOTE

Extinction coefficients for the chromophore MUST be obtained from the reagent manufacturer or determined experimentally (refer to Paragraph 8.5).

T.V. = Total reaction volume (i.e., sample plus reagent)

S.V. = Sample volume

0.5 = Cuvette pathlength

1000 = Units correction factor

MATH MODEL

Options: Linear

Math model 1 A four parameter log-logit function
Math model 2 A five parameter logit function
Math model 3 A five parameter exponential function
Math model 8 A five parameter logit function

Math model 9 A four parameter log-logit function

(Refer to Paragraph 4.8.2.1 for detailed explanation of each selection.)

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NUMBER OF CALIBRATORS

Allowable Entries: Use SELECT to choose 0, 1, 2, 5 or 6

If 0 is entered, a calculation factor is required. There can be no more than 2 calibrators for a linear math model. (Refer to Paragraph 4.8 for calibration theory.)

If 2 or more calibrators are entered, span values are displayed. If 5 or more calibrators are entered, recovery and sensitivity statistics are also displayed.

CALIBRATOR VALUES

Allowable range: 0.0 to 9999.9

The values must be in the same units as specified in the UNIT parameter. Enter the values for the number of calibrators stated above in ascending order. This will facilitate proper placement of the calibration samples on the sector (lowest to highest), since the load list does not denote the cup order of the user defined calibrators. All other values will be disregarded. No calibrator value should be entered if a CALCULATION FACTOR is designated.

CALIBRATION TIME LIMIT

Allowable range: 0.0 to 336.0

Number of hours the chemistry can be run before recalibration is required. Operator will be alerted and the results flagged if this time is exceeded. Parameter not applicable if calculation factor is designated. (Refer to Paragraph 6.3 for calibration procedures.)

WAVELENGTH (Primary and Secondary)

Options:	340	560
	380	600
	410	650
	470	670
	520	700

The primary wavelength is the wavelength at which the desired chromophore is to be measured. The secondary wavelength is the wavelength used for flash correction of the primary absorbance values. The same wavelength cannot be used more than once per test. (Refer to Paragraph 8.4 for Wavelength Selection Information.)

PRIMARY INJECT REAGENT 1

Options: A or B

Designates the compartment of the cartridge which will be pipetted first. The first primary reagent must be located in the largest compartment if more than one reagent is required.

VOLUME

Allowable range: 125 to 327 µL

The volume of the first primary reagent is entered in 1 µL increments.

NOTE

If primary inject reagent 2, or secondary reagent are not used, the volume input field displays <NONE>, and cannot be modified.

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PRIMARY INJECT REAGENT 2

Options: NONE, A, B or C

Primary Reagent 2 is dispensed at the same time as Primary Reagent 1.

VOLUME

Allowable Range: 6 to 75 µL

The volume is specified in 1 μ L increments.

The combined volume of the primary inject reagents must be greater than or equal to 200 µL.

SECONDARY INJECT REAGENT

Options: NONE, B or C

Compartment from which a starter reagent is pipetted. The starter is added after primary reagents and/or sample have been added to the reaction cuvette.

VOLUME

Allowable Range: 6 to 75 µL

Volume is specified in 1 μ L increments.

ADD TIME

Allowable Range: 0 to 975 seconds

The secondary inject reagent may be added a minimum of 16 seconds after primary reagent(s) and/or sample have been pipetted. Thereafter, the secondary reagent may be added at 32 second intervals. Time is entered in increments of 1 second; however, the reagent will be added at the 32 second interval closest to the time defined. Add Time must be 0 seconds if there is no secondary inject reagent required (Figure 8-3).

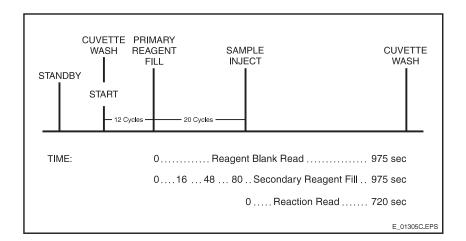


Figure 8-3. Add Time

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SAMPLE VOLUME

Allowable Range: 3 to 25 µL

Volume specified in 1 μL increments. Total volume of sample and reagents A, B, and C cannot exceed 330 μL.

REAGENT BLANK READ TIMES

Allowable Range: START READ 0 to 975 seconds

END READ 0 to 975 seconds

Time 0 is when reagent is added to the cuvette (Figure 8-3). Reagent addition cycle time is 16 seconds; however, time is entered and read in 1 second intervals. It is recommended that the reagent blank be read before sample is added. Sample is added approximately 5.5 minutes or 320 seconds after reagent addition.

REACTION READ TIMES

Allowable Range: START READ 0 to 720 seconds

END READ 0 to 720 seconds

Time 0 begins after sample has been added to the cuvette (Figure 8-3). Time is entered and read in 1 second intervals.

USABLE RANGE

Allowable Range: LOWER LIMIT 0 to 99999

UPPER LIMIT 0 to 99999

Specifies the analytic range of the reagent. Results will be suppressed and flagged as out-of-instrument range low (OIR-LO) or out-of-instrument range high (OIR-HI) respectively if these ranges are exceeded. (Exception: Therapeutic drugs assays. Results will be suppressed and flagged as OIR).

ERROR DETECTION LIMITS

An absorbance of 1.5 with a 0.5 cm pathlength corresponds to an absorbance of 3.0 with a 1 cm pathlength.

REAGENT BLANK

Allowable Range: LOW ABS LIMIT -1.500 to 1.500

HIGH ABS LIMIT -1.500 to 1.500

Specifies acceptable minimum and maximum absorbances for the reagent blank measured during the blank read window. If these values are exceeded, the results are suppressed and flagged as blank absorbance high (BL ABS HI) or blank absorbance low (BL ABS LO).

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Table 8-1. User-Defined Chemistry Setup Parameters (Continued)

REACTION

Allowable Range: LOW ABS LIMIT -1.500 to 1.500

HIGH ABS LIMIT -1.500 to 1.500

Specifies acceptable minimum and maximum absorbances. For upgoing rate or endpoint reactions, if the reaction absorbance is less than the LOW ABS LIMIT then results will be suppressed and flagged as "RX ABS LO". Likewise, if the High ABS Limit is exceeded, the result is suppressed and flagged as "RX ABS HI".

For downgoing rate reactions, the LOW ABS LIMIT indicates the minimum absorbance obtainable at the linear limit or dynamic range high for the reagent. The HIGH ABS LIMIT, when measured just after start reagent or sample is added, serves as an indicator of sample integrity. When this value is exceeded, results will be suppressed and flagged "Initial Absorbance High (INT ABS HI)".

SUBSTRATE DEPLETION

Allowable Range: INITIAL RATE -99.999 to 99.999

Specifies maximum rate of absorbance change measured within the first cycle after sample or secondary reagent is added. When this value is exceeded, results will be suppressed and flagged "Initial Rate High (INT RATE HI)".

Allowable Range: DELTA ABS -1.500 to 1.500

A measure of substrate depletion for rate reactions. Specifies the maximum acceptable difference between the Reaction HIGH ABS, measured just after sample or starter reagent addition, and the final absorbance measured at the end of the reaction read window. When this value is exceeded, results will be suppressed and flagged "substrate depletion (SUB DEPL)".

MULTIPOINT SPANS

Allowable Range: -1.500 to 1.500

Specifies allowable difference in absorbance between respective multipoint calibrator levels:

1 and 2 3 and 4 5 and 6 2 and 3 4 and 5 6 and 1

Values will only be displayed for the number of calibrators specified under "# of Calibrators". A change in calibrator number will reset the spans to their default values (0.00).

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RECOVERY/SENSITIVITY

The Recovery and Sensitivity error check evaluates the integrity of a multipoint calibration curve. The Recovery Test determines whether the recovery errors are too large for a calibration curve to be useful. The Sensitivity Test determines whether the calibration curve has enough sensitivity throughout the dynamic range in order to be useful. "Sensitivity" is how much the instrument reading changes for a given change in concentration. Each of the two tests yields an estimate of the magnitude of a particular error in the calculated concentration corresponding to a particular instrument reading. In order to make the estimated error meaningful, the error is compared with a designated precision specification from which a "scaled error" is calculated:

 $\mbox{scaled error} = \frac{\mbox{error in concentration}}{\mbox{precision specification}}$

The scaled errors are used as a basis to judge whether a calibration curve is fit to use.

The recovery errors are calculated for each setpoint as the difference between the recovery concentration and the actual concentration. The scaled recovery errors are then computed for each setpoint. The calibration curve is then judged on the worst (highest) scaled recovery error and the root-mean-square (RMS) of the scaled recovery errors.

The sensitivity error at any point along the calibration curve is calculated by dividing the noise of the instrument readings by the slope of the calibration curve. The scaled sensitivity errors are then computed for the curve.

STD DEV (CONC)

Allowable Range: 0.00 to 9999.99

This number (in concentration units) is estimated by the standard deviation during precision runs.

CV (%)

Allowable Range: 0.00 to 99.99

This number (in percentage units) is estimated by data obtained during precision runs.

STD DEV (mA)

Allowable Range: 0.00 to 99.99

This number (in mA or mA/min) is estimated by the standard deviation of the absorbance readings during precision runs. It is an indicator of instrument noise.

THRESHOLD

Allowable Range: 0.00 to 9999.99

The concentration at which the sensitivity test need not be as demanding for values above the "threshold".

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8.4 WAVELENGTH SELECTION

The Synchron CX4 Systems provide a selection of ten wavelengths ranging throughout the UV-visible spectral region from which to measure the absorbance of a desired analyte. These are 340, 380, 410, 470, 520, 560, 600, 650, 670, and 700 nm. In order to run a user-defined chemistry, two wavelengths are required, the primary or analysis wavelength and the secondary or reference wavelength. The primary wavelength is selected based on the maximum absorbance peak obtained using the desired chromophore. The secondary wavelength, which will vary depending on the properties of the chromophore, is used to compensate for variations in the light intensity each time the xenon lamp is flashed. For a detailed description of the principles of flash correction, refer to Paragraph 4.4.2. For additional information on proper wavelength selection, refer to Modern Optical Methods of Analysis, Eugene D. Olsen, 1975.

Knowledge of the spectral curve of the chromophore of interest will facilitate proper selection of these wavelengths. To select the optimal secondary wavelength for a given analyte, the following criteria are recommended:

- 1. The secondary wavelength should be as close to the primary wavelength as possible without overlapping the spectral curve of the desired chromophore. In essence, the reference wavelength should be near the base of the analytical absorption curve. If the wavelength selected resides on the spectral curve, a loss of sensitivity may result.
- 2. In order to minimize any optical interference due to the presence of another absorption curve, the selection of the secondary wavelength will depend on the location of the other curve in relation to the primary wavelength of the desired chromophore. If the second curve overlaps the primary wavelength, there may be an interference; however, proper selection of the secondary wavelength can function as a "bichromatic" measurement effectively minimizing or eliminating absorbance due to the interfering substance. In this instance, the secondary wavelength should be on the interfering curve at or near a point where the absorbance is at the same level as the crossover absorbance on the primary wavelength. If, however, the second curve does not interfere at the primary wavelength, the secondary wavelength should not be selected within the area encompassed by that curve.
- 3. The shortest distance between the two selected wavelengths (without overlapping the spectral curve) optimizes the flash characteristics of the lamp providing better precision of the absorbance data. It is strongly recommended that precision and correlation data be accumulated to verify proper selection of the wavelengths as well as all of the defined parameters.

8.5 DETERMINATION OF EXTINCTION COEFFICIENTS

In general, there are two ways of determining the molar absorptivity or extinction coefficient for a given chemistry at each of the wavelengths required for the user-defined setup. They are as follows:

1. Prepare a stock standard solution of the chromophore. From this stock solution, prepare a working standard solution at the same molar concentration recommended by the reagent manufacturer. Obtain absorbance values for this working standard solution within a narrow-bandpass manual spectrophotometer which utilizes 1 cm pathlength cuvettes. Calculate the extinction coefficient (e) for the appropriate wavelength as follows:

 $e = \frac{Absorbance of chromophore}{Concentration of working std. solution (mmol/L)}$

For additional information, refer to Textbook of Clinical Chemistry, Norbert W. Tietz, 1994. This method may only be used when the chromophore is measurable in a stable form. When the chromophore is not attainable in a stable form and may only be measured in a dynamic state then the second method of determining extinction coefficients is suggested.

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2. Prepare the reagent according to the manufacturer's package insert instructions. With a manual spectro-photometer or automated instrument, obtain the delta absorbance per minute on at least ten replicates of a normal or high normal sample at each of the appropriate wavelengths selected. Average the delta absorbance per minute obtained at each wavelength. The extinction coefficient at the secondary wavelength may be calculated by use of a factor or correction coefficient (R) derived from the ratio of the delta absorbance per minute at the secondary and primary wavelengths. The following formula may be used:

$$e^2 = e^1 \times R$$

where:

e² = Extinction coefficient at the secondary wavelength

e¹ = Extinction coefficient at the primary wavelength

R = Delta absorbance/minute at secondary wavelength Delta absorbance/minute at primary wavelength

NOTE

The extinction coefficient of the chromophore at the primary wavelength is usually specified by the manufacturer in the reagent package insert.

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SCHEDULED MAINTENANCE

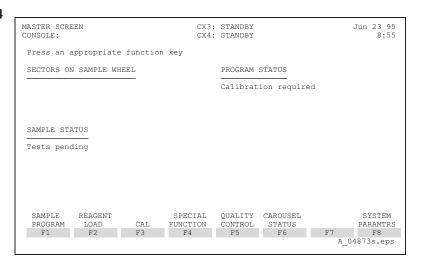
This section contains the information necessary to perform the periodic maintenance procedures on the SYNCHRON CX4 and CX7 Systems. It is important that the suggested maintenance be performed when scheduled to ensure reliable system performance. Maintenance Kits are provided with sufficient supplies to complete scheduled maintenance for one year. For specific maintenance kit part numbers see Section 12 PARTS AND SUPPLIES.

In addition, an Instrument Log Book (P/N 249005) is provided for quick reference and documentation of completed procedures.

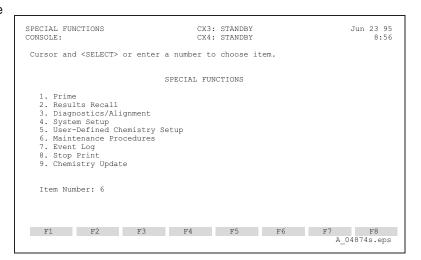
If preventive maintenance is ignored, the system may continue to function for some time before becoming inoperable. During this period, however, system precision and accuracy could become questionable. A schedule of preventive maintenance procedures is shown in Table 9-1 and is supplemented with step-by-step instructions in the following paragraphs.

Certain components of the system require that they be positioned, operated or disabled using the instrument computer for preparation. Procedures are accessed as follows:

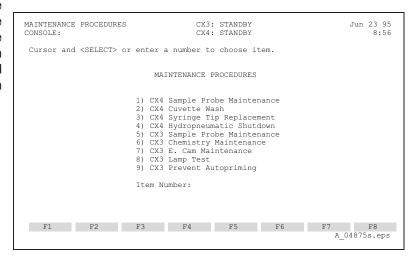
1. From the MASTER Screen, press **F4 SPECIAL FUNCTION**.



2. Cursor and **SELECT** 6. Maintenance Procedures or type **6** and **ENTER**.



3. The computer-assisted maintenance procedures are displayed. Select the desired procedure and follow the steps on the screen. Upon completion and exit of the procedure, all affected components are homed. Details on each procedure are described below:



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SYNCHRON CXº4CE/CX4 DELTA AND SYNCHRON CXº7/CX7 DELTA CLINICAL SYSTEMS SCHEDULED MAINTENANCE

SYNCHRON CXº7/CX7 DELTA CLINICAL S	SYSTEMS SCHEDULED MAINTENANCE	MONTH:	YEAR:
	DAILY		Operating Instructions*
Wipe	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	20 21 22 23 24 25 26 27 28 2	references
Outside of all probes and mixers	CX4		9.1.6
Outside of CX3 sample probe, and clean interior with cleaning stylus	CX3		9.1.9
Check			
STATUS MONITOR Screen for error conditions	CX4		9.1.2
	CX3		9.1.2
 Syringe plunger rods with attached tips for wear; replace if necessary 	CX4		9.1.5
Hydropneumatic gauges for proper settings	CX4		9.1.4
Wash concentrate, probe rinse solution and CX3	CX4		9.1.1
reagent levels and expiration dates; replace if needed	CX3		9.1.7
			
 Fluid level of damper assemblies; adjust if needed to 1/2 to 3/4 full 	CX3		9.1.8
 Condition and orientation of cuvette wipers; adjust or replace if needed 	CX4		9.1.3
Prime			
CX3 reagents and observe for leaks, crimps and proper movement of assemblies	CX3		9.1.10
	<u> </u>		

		WEEKLY				Operating Instructions*
Inspect In-line filters at peri-pump assemblies; clean or replace if needed	CX3 Week 1 Initial	Week 2 Date / Initial	Week 3 Date / Initial	Week 4 Date / Initial	Week 5 Date / Initial	references
Flush CX4 sample and reagent pickup probes	CX4					9.2.1
Adjust Pinch valve tubing for C cam, E cam and solenoid valves; check C cam vent line #124	схз					9.2.3
Bleach Calcium reaction cup and stirrer (CA cup users only)	CX3					9.2.4

^{*} SYNCHRON CX4CE/CX7 and CX4/CX7 DELTA Clinical Systems Operating Instructions 015-248408

SYNCHRON CXº4CE/CX4 DELTA AND SYNCHRON CXº7/CX7 DELTA CLINICAL SYSTEMS SCHEDULED MAINTENANCE

SYNCHRON CXº7/CX7 DELT	A CLINICAL SYSTEMS SCHEDU	JLED MAI	NTENANCE	MONTH	H:	YEA	\R:
Clean	TWO-WEEK Date/Initial Date/Initial Date/Initial Date/Initial	Operating Instructions* references	Replace	TWO-MONTH (Continued)	1		Operating Instructions* references
• Flow cell with 50% bleach †	CX3	9.3.4	Silicone wipers on cuvette for proper operation of cuv-		CX4		9.5.2
Glucose electrode, reaction cup and stirrer; Recharge electrode	CX3	9.3.2	ioi proper operanen er car	0.10 Mac/101 p. 0200			
Creatinine reaction cup and stirrer	CX3	9.3.3	CX3 peri-pump tubing		CX3		9.5.3
Total Protein reaction cup and stirrer (TP cup users only) If >350 samples per day, perform weekly.	СХЗ	9.3.1	In-line filters at peri-pump a	assemblies	CX3		9.5.4

MONTHLY			Operating Instructions* references
Replace		Date / Initial	1616161663
In-line filter at probe rinse solution	CX4		9.4.4
Alkaline Buffer peri-pump tubing and Alkaline Buffer reagent	СХЗ		9.4.6-7
Check			
Proper operation of refrigerator circulation fan and for condensation or ice buildup	CX4		9.4.1
Clean			
Reagent bar code reader window	CX4		9.4.2
Refrigerator and power supply air filters	CX4		9.4.3
Sample bar code reader window	CX4		9.4.5
BUN electrode, reaction cup and stirrer	СХЗ		9.4.8

TWO-MONT Check • All diluted wash bottles, DI water bottle, probe rinse bottle and float sensors for contamination (Refer to Six-Month Maintenance if growth is noted) Clean	H CX4	Date / Initial	Operating Instructions* references 9.5.1
Chloride electrode	CX3		9.5.5
CX3 Electronics compartment and power supply compartment air filter; Replace if needed (Continued at top of page)	CX3		9.5.6

THREE-MON	NTH		Operating Instructions* references
Replace		Date / Initial	
Sample and reagent syringe plunger rods with attached tips	CX4		9.6.1-2

SIX-MONTI	Ins	perating tructions* ferences	
Replace • Wash concentrate in-line filter	Date CX4	/ Initial	9.7.1
Potassium electrode tip	CX3		9.7.3
Calcium electrode tip (Ca ISE users only)	СХЗ		9.7.4
Inlet water filter (on back of instrument)			9.7.6
Ratio pump quad-rings	CX3		9.7.7
Clean			
All diluted wash bottles, probe rinse bottle and float sensors	CX4		9.7.2
Electrolyte drain	СХЗ		9.7.5

^{*} SYNCHRON CX4CE/CX7 and CX4/CX7 DELTA Clinical Systems Operating Instructions 015-248408

SYNCHRON CXº5CE/CX5 DELTA CLINICAL SYSTEMS SCHEDULED MAINTENANCE

MONTH: Y	EAR:
----------	------

AS-NEEDED

Date	Serviced By	Problems Observed	Description of Maintenance or Service

1. CX4 Sample Probe Maintenance

This procedure removes the power to the CX4 sample probe. The following procedures require this function:

(a) Internally Clean Sample and Reagent Pick-up Probes (Paragraph 9.2.1).

2. CX4 Cuvette Wash

The Cuvette Wash procedure automatically washes all 80 cuvettes at an accelerated rate (approximately 10 minutes). Before running this procedure, ensure that wash bottles are full by priming Fill Wash Bottles (Paragraph 9.7.2, step 11). The Cuvette Wash procedure is primarily used for the following:

(a) Final clean-up of the cuvettes if the last run of the system was completed by pressing PAUSE.

NOTE

Pressing **PAUSE** allows the system to complete the processing of all cuvettes containing reagent or sample but the system goes into **STANDBY** without cleaning the cuvettes.

3. CX4 Syringe Tip/Plunger Replacement

This procedure prepares the sample and reagent syringe plunger for replacement or maintenance by extending the plunger to the bottom of the glass barrel for easy removal. The following procedures require this function:

- (a) Check Syringe Plunger rods with attached Tips (Paragraph 9.1.5).
- (b) Replace Sample Syringe Plunger Rod with attached Tip (Paragraph 9.6.1).
- (c) Replace Reagent Syringe Plunger rod with attached Tip (Paragraph 9.6.2).
- (d) Replace Sample Syringe Plunger Tip (Paragraph 9.8.20).
- (e) Replace Reagent Syringe Plunger Tip (Paragraph 9.8.20).

4. CX4 Hydropneumatic Shutdown

This procedure turns off the power to the hydropneumatic system thereby releasing the pressure in all applicable bottles or reservoirs. The following procedures require this function.

- (a) Check Level of Wash Concentrate and Probe Rinse Solution (Paragraph 9.1.1).
- (b) Replace Probe Rinse Solution In-Line Filter (Paragraph 9.4.4).
- (c) Check All Diluted Wash Bottles and Float Sensors for Contamination (Paragraph 9.5.1).
- (d) Replace Wash Concentrate In-Line Filter (Paragraph 9.7.1).
- (e) Clean Wash Bottles and Float Sensors (Paragraph 9.7.2).

CAUTION

The hydropneumatic system may automatically start during CX3 autoprime.

5. CX3 Sample Probe Maintenance (CX7 Users Only)

This procedure repositions/rotates the CX3 sample probe to allow easy access. The following procedures require this function:

- (a) Clean Sample Pick-up Probe (Paragraph 9.1.9).
- (b) Replace the Quad-ring in Electrolyte Injection Cup (Paragraph 9.8.6).
- (c) Any procedure which requires removal of rear chemistry cup shield.

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6. CX3 Chemistry Maintenance (CX7 Users Only)

This procedure drains the chemistry reaction cup of reagent and prepares it for cup maintenance. The following procedure requires this function:

- (a) Clean BUN Electrode, Chemistry Reaction Cup and Stirrer (Paragraph 9.4.8).
- (b) Recharge Glucose Electrode and Clean Chemistry Reaction Cup and Stirrer (Paragraph 9.3.2).
- (c) Bleach Calcium Chemistry Reaction Cup and Stirrer (Cup Users Only) (Paragraph 9.2.4).
- (d) Clean Creatinine Chemistry Reaction Cup and Stirrer (Paragraph 9.3.3).
- (e) Clean Total Protein Reaction Cup and Stirrer (TP Cup Users Only) (Paragraph 9.3.1).

7. CX3 E Cam Maintenance (CX7 Users Only)

This procedure rotates the pinch valve E cam to position 5 thereby releasing the pressure on the tubing. The following procedure requires this function:

(a) Adjust Pinch Valve Tubing (Paragraph 9.2.3)

8. CX3 Lamp Test (CX7 Users Only)

This procedure performs a test on the Creatinine and Calcium or Total Protein chemistry reaction cup lamps. This feature is not used in any of the scheduled maintenance procedures but is required in the Diagnostics and Troubleshooting Guide (Section 4).

9. CX3 Prevent Autoprime (CX7 Users Only)

This procedure prevents the system from autopriming. The following procedures require this function:

- (a) Clean/inspect In-line Filters at Peri-Pump Assemblies (Paragraph 9.2.2).
- (b) Enzymatic cleaning of the Flow Cell and Electrolyte Injection Cup (Paragraph 9.8.12 and 9.8.13).
- (c) Clean Chloride Electrode (Paragraph 9.5.5).
- (d) Replace Alkaline Buffer Peri-Pump Tubing (Paragraph 9.4.6).
- (e) Replace Peri-Pump Assembly In-line Filters (Paragraph 9.5.4).
- (f) Replace Potassium Electrode Tip (Paragraph 9.7.3).
- (g) Clean Electrolyte Drain (Paragraph 9.7.5).
- (h) Replace Five-stage Ratio Pump Quad-rings (Paragraph 9.7.7).
- (i) Replace CO₂ Measuring Electrode Membrane (Paragraph 9.8.5).
- (j) Replace Calcium Electrode Tip (CALC ISE Users only) (Paragraph 9.7.4).
- (k) Replace Peri-Pump Tubing (Paragraph 9.5.3)

NOTE

After completion of any CX3 maintenance procedure, a successful calibration MUST be performed prior to operation of the system.

9.1 DAILY MAINTENANCE PROCEDURES

CX4:

9.1.1 Check Level of Wash Concentrate and Probe Rinse Solution

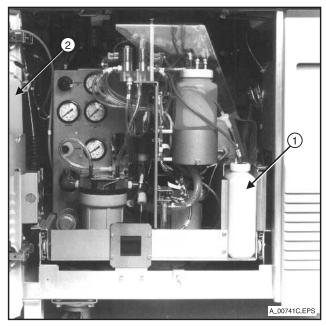
NOTE

The Wash Concentrate and Probe Rinse Solution are monitored with float (level) sensors. If either bottle is flagged as low (an error window is posted), the system will stop dispensing reagent, complete tests already in progress, and go to a standby condition.

- Open the lower middle (left) compartment door and check the level of the wash concentrate and probe rinse solution (Figure 9-1). If fluid levels are adequate, proceed to step 2. If fluid level(s) is/are low, replace bottles as follows:
 - (a) Release the pressure from the bottles as follows:
 - From the MASTER Screen, press F4 SPECIAL FUNC-TION.
 - ii. Cursor and SELECT 6. Maintenance Procedures or type 6 and ENTER.
 - iii. Cursor and SELECT 4) CX4 Hydropneumatic Shutdown or type 4 and ENTER.

NOTE

To release residual pressure, loosen the cap on the wash concentrate bottle. Always wear eye protection and rubber gloves when performing this procedure.



- 1 Wash Concentrate Bottle
- 2 Probe Rinse Bottle

Figure 9-1. Wash Concentrate and Probe Rinse Solution Levels

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- (b) If replacing the WASH CON-CENTRATE:
 - Remove the empty bottle and discard.
 - ii. Place float sensor in new bottle of wash concentrate (P/N 450160). No preparation is required.
 - iii. Place bottle on system.
- (c) If replacing the PROBE RINSE SOLUTION:
 - i. Remove the empty bottle and rinse with deionized water.
 - ii. Place 750 mL deionized water into empty cleaned bottle.
 - iii. Pour entire contents (250 mL) of concentrated probe rinse solution (P/N 443735) into the bottle.
 - iv. Replace float sensor and gently invert. Replace bottle on system.
- (d) Press **PREV SCREEN** to conclude this procedure.
- 2. Close the compartment door.

9.1.2 Check Status Monitor

- To access the STATUS MONITOR Screen program the system as follows:
 - (a) From the MASTER Screen, press **F8 SYSTEM PARAMTRS**.
 - (b) Press F7 STATUS MONITOR.
 - (c) Press F6 CX4 P.S. STATUS.

 Check each category. A red value indicates the presence of an out-ofrange condition. To resolve an error condition, refer to the Diagnostics and Troubleshooting Guide (Section 2).

NOTE

Step 3 applies to CX7 users only. CX4 users proceed to Step 4.

 Press F5 CX3 P.S. STATUS and repeat Step 2. For CX7 DELTA Systems, press F3 CX3 DELTA P.S. STA-TUS. Then perform Step 4.

NOTE

For CX7 DELTA Systems only:

The acceptable specification for Power Supply 1, +12V 'M' is 11.8 - 13.4.

The acceptable specification for Power Supply 2, +12V is 11.4 - 12.6

For both CX7 and CX7 DELTA Systems:

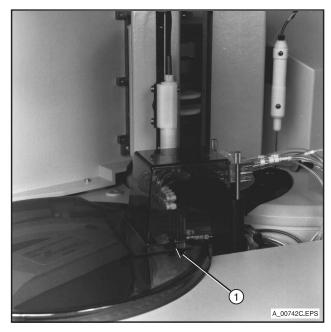
Typically, out of range readings display in red. The actual readings may display in red when they are in range, or may display white when they are out of range. Disregard the display color and verify the actual readings are within the above specification. Out of range readings indicate an error condition.

4. Press **PREV SCREEN** to conclude procedure.

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9.1.3 Check Condition and Orientation of the Cuvette Wipers

- Remove wash station cover by pulling up on the locking pins (one on each side) and pulling the cover straight up and off (Figure 9-2).
- Check the silicone wipers on cuvette washer probes 5 and 6 for proper orientation to the cuvettes. The tips should be square to the cuvette. The undersurface of the wipers should be flush with the end of the washer probes. Adjust if necessary.



1 - Locking Pin

Figure 9-2. Cuvette Wash Station Cover

- Observe for tears or rips on the edges of the wipers (Figure 9-3). Replace if necessary (Refer to Paragraph 9.5.2).
- 4. Replace wash station cover.



Figure 9-3. Silicone Wipers

9.1.4 Check Hydropneumatic Gauges

- 1. Open the middle compartment door.
- Check the gauges for proper settings. (Figure 9-4) (For easy reference, each gauge has a green marker to indicate proper range). Digital gauge readings may be checked by following these steps:
 - (a) From the MASTER Screen, press the **F8 SYSTEM PARAMTERS** key.
 - (b) Press **F7 STATUS MONITOR** key.

If any Pressure/vacuum readings (DI water pressure, Air pressure, vacuum) appear in red, or gauge readings are out of specifications, proceed to Step 4.

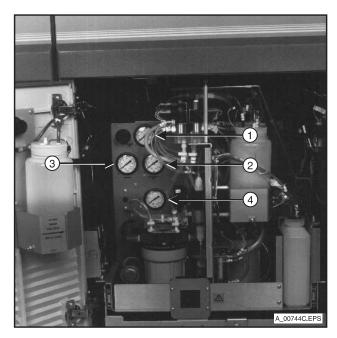
3. If gauges are within specification, proceed to Step 5.

NOTE

The compressor must be on and the system in STANDBY before assessing gauge settings. If the compressor is off, prime any CX4 prime module to activate. The compressor may also be activated by pressing the HOME key. Be sure that all bottle caps are tight with no air leaks.

Specifications:

1. Primary Air 25.0 psig ± 1.0 psig 2. Secondary Air 5.0 psig ± 0.5 psig 3. Vacuum 27.0 in Hg minimum 4. Deionized Water 10.0 psig ± 0.5 psig



- 1 Primary Air
- 2 Secondary Air
- 3 Vacuum
- 4 Deionized Water

Figure 9-4. Hydropneumatic Gauges

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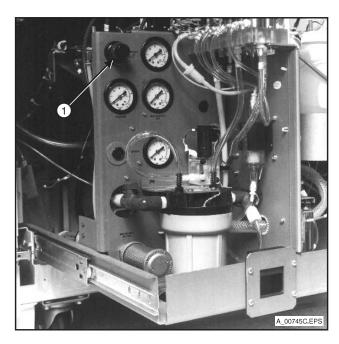
- 4. For gauges out of specification.
 - (a) For PRIMARY AIR:
 - i. Depending upon the knob, either:

Rotate the locking screw counter-clockwise while holding the knob. This unlocks the knob. Turn the knob until the gauge is within specification. Hold the knob and retighten the center locking screw when adjustments are complete.

or

Pull the knob forward to unlock. Turn the knob until the gauge is within specification. Push the knob in until it clicks to lock (Figure 9-5).

- ii. Residual pressure may not allow much movement in gauge. To release the residual pressure internally and externally, prime as follows:
 - (a) From the MASTER Screen, press **F4 SPECIAL FUNCTION**.
 - (b) Cursor and **SELECT** 1. Prime or type **1** and **ENTER**.
 - (c) Cursor and **SELECT**External Probe Wash and Internal Probe
 Wash.
 - (d) Press **F1 START PRIME**.
- iii. Observe the gauge to check if it is within specification. Repeat Steps i and ii if necessary. If the gauge reading is still out of specification, call your local Beckman office for assistance (North American Customers, call 1-800-854-3633).

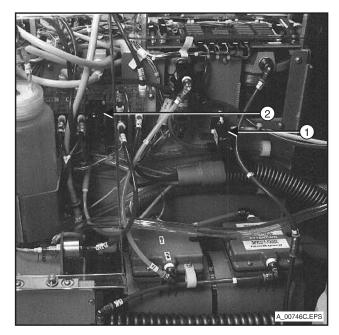


1 - Primary Air Adjustment Knob

Figure 9-5. Primary Air Adjust Knob

(b) For SECONDARY AIR:

- If no adjustment hole is present, remove the plastic cover over the hydropneumatic system.
- ii. Using a standard screwdriver, adjust the valve until the gauge is within specification (Green marker indicates proper range) (Figure 9-6).
- iii. Residual pressure may not allow much movement in gauge. Release the residual pressure by pressing down on the autoloader solenoid (relief) valve button (Figure 9-6).
- iv. Observe the gauge to check if it is within specification. Repeat Steps ii and iii if necessary. If the gauge reading is still out of specification (Green marker indicates proper range), call your local Beckman office for assistance (North American Customers, call 1-800-854-3633).
- v. Replace the plastic cover, if removed.



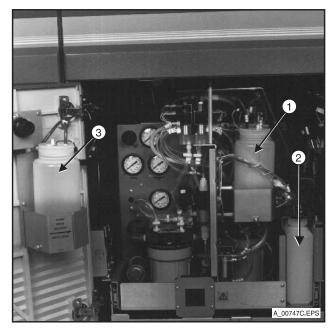
- 1 Autoloader Solenoid Valve
- 2 Secondary Air Valve

Figure 9-6. Secondary Air

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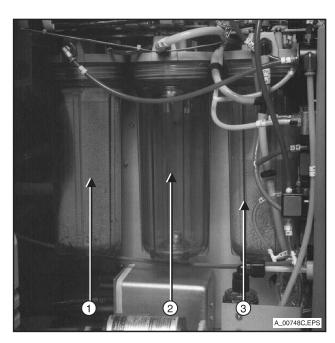
(c) For VACUUM:

- i. Tighten the caps of the following bottles to eliminate any possible leak (Figures 9-7 and 9-8):
 Dilute wash bottles
 Wash Concentrate Bottle
 Probe Rinse Solution Bottle
 Liquid Trap Reservoir
 Vacuum Reservoir
 Air Reservoir
- If the gauge reading is still out of specification, call your local Beckman office for assistance (North American Customers, call 1-800-854-3633).



- 1 Dilute Wash Bottles
- 2 Wash Concentrate Bottle
- 3 Probe Rinse Solution Bottle

Figure 9-7. Vacuum Checks

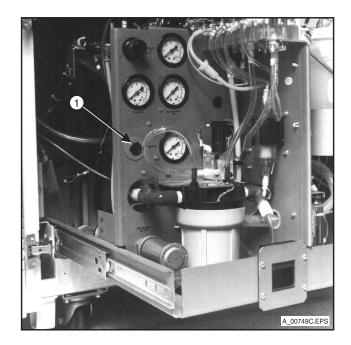


- 1 Air Reservoir
- 2 Vacuum Reservoir
- 3 Liquid Trap Reservoir

Figure 9-8. Vacuum Checks

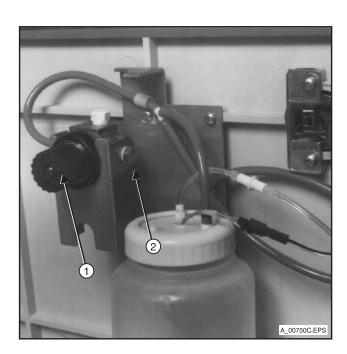
(d) For DEIONIZED WATER:

- Using a standard screwdriver, turn the deionized water valve until the gauge reads 10 psig (Figure 9-9A).
- ii. Residual pressure to the deionized water is regulated by a bleed port. To set properly, turn the relief valve located by the probe rinse solution bottle counterclockwise until the water gauge reads approximately 9.5 psig (Figure 9-9B).
- iii. Slowly turn the same relief valve clockwise until the gauge reads 10 psig again.
- 5. Press **PREV SCREEN** to conclude this procedure.
- 6. Close the compartment door.



Α

1 - DI Water Valve



В

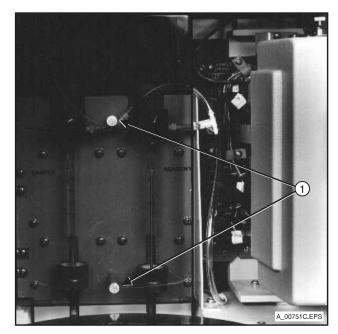
- 1 Relief Valve
- 2 Air Bleed Port

Figure 9-9. DI Water Valves

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9.1.5 Check Syringe Plunger Rods with attached Tips for Wear

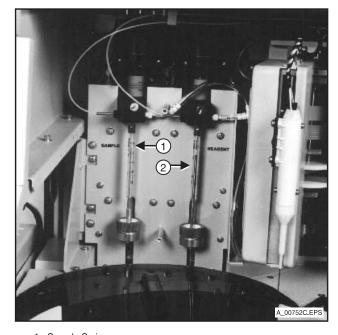
- Remove syringe cover by removing thumbscrews (Figure 9-10). Be careful not to drop thumbscrews into spill trough as retrieval may be difficult.
- 2. Fully extend the plungers to the bottom of the syringe barrels by programming the system as follows:
 - (a) From the MASTER Screen, press **F4 SPECIAL FUNCTION**.
 - (b) Cursor and **SELECT** 6. Maintenance Procedures or type **6** and **ENTER**.
 - (c) Cursor and **SELECT** 3) CX4 Syringe Replacement or type **3** and **ENTER**.



1 - Thumbscrews

Figure 9-10. Thumbscrews

- Check the tip of the sample and reagent plungers for signs of wear and observe for any particles inside the barrel (Figure 9-11). Replace plunger rod & tip, if necessary (Refer to Paragraph 9.6.1 and 9.6.2).
- 4. Press **PREV SCREEN** to conclude procedure.
- Replace syringe cover and secure thumbscrews.

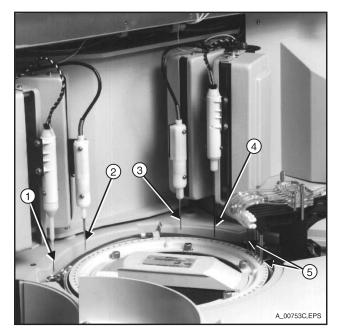


- 1 Sample Syringe
- 2 Reagent Syringe

Figure 9-11. Syringe Plunger Tips

9.1.6 Externally Clean All Probes and Mixers

- Thoroughly wipe outside and bottom of sample probe and mixer, reagent probe and mixer, and cuvette washer probes 1, 2, 3, 4 using lintless tissue moistened with a 10% dilution of Trace-Klean (P/N 589784) (Figure 9-12).
- 2. Repeat step 1, thoroughly cleaning probes and mixers with distilled water.
- 3. Repeat step 1, using 70% isopropanol.
- 4. Press **SYS HOME** when completed.



- 1 Sample Probe
- 2 Sample Mixer
- 3 Reagent Mixer
- 4 Reagent Probe
- 5 Cuvette Washer Probes

Figure 9-12. Clean Probes and Mixers

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9.1.7 Check CX3 Reagent Levels and Expiration Dates (CX7 Users Only)

Open CX3 reagent-compartment door (far left) and check the level of all the reagent bottles (Figure 9-13). Check the expiration dates on all reagents. If reagent is low or expired, replace as follows:

CAUTION

CX3 wash solution must be prepared at least 24-hours before use. Prepare wash solution as directed in the wash concentrate package insert or on the 10-liter wash solution bottle provided. Cap loosely and wait 24-hours (to allow outgassing to occur) before loading onto system.

NOTE

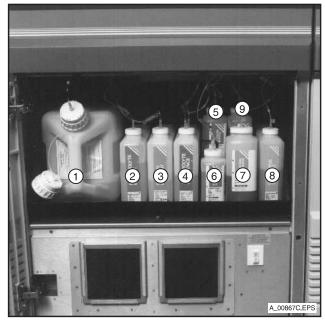
Alkaline Buffer solution is recycled and will remain full. It should be replaced monthly. Refer to Paragraph 9.4.7 for instructions.

- 1. Remove empty or expired reagent bottle.
- 2. Unscrew cap and remove reagent straw(s).

NOTE

Never combine remaining reagent with new reagent.

- 3. Place reagent straw(s) in new reagent bottle and secure cap.
- 4. Place new reagent bottle in reagent compartment.
- 5. Load new reagent onto the system as follows:
 - (a) From the MASTER Screen, press **F2 REAGENT LOAD**.
 - (b) Press F3 CX3 LOAD.
 - (c) Cursor and **SELECT** CX3 reagent to be loaded.



- 1 Wash Bottle
- 2 Electrolyte Buffer
- 3 CO₂ Acid Reagent
- 4 Electrolyte Reference
- 5 Alkaline Buffer
- 6 CX3 BUN
- 7 CX3 CA
- 8 CX3 CRE 9 - CX3 GLU

Figure 9-13. CX3 Reagent Compartment

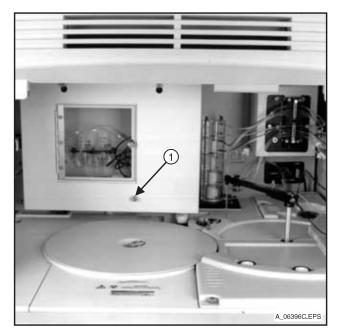
- (d) Press F4 CONTINUE.
- (e) Press F1 PRIME.
- 6. Press **PREV SCREEN** to conclude this procedure.
- 7. Close CX3 reagent compartment door.

9.1.8 Check Fluid Level of Damper Assemblies (CX7 Users Only)

The damper assemblies prevent bubbles from entering the flow cell and dampen any reagent pulsations caused by the peri-pumps which deliver reagent to the flow cell. In order to function properly, these damper assemblies must be approximately one-half to three-fourths full with their respective reagents.

Check the damper assemblies to verify that they are half full with the appropriate reagent as follows:

- 1. Remove the flow cell cover as follows:
 - (a) Loosen the captive screw at the bottom of the flow cell cover (Figure 9-14).
 - (b) Grasp the flow cell cover.
 - (c) Carefully lift up and over the two fixed guide screws.
 - (d) Set the cover aside for later reinstallation.



1 - Captive Screw

Figure 9-14. Removing Flow Cell Cover

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- Verify that both the CO₂ alkaline buffer damper (left) and the electrolyte reference damper (right) are approximately one-half to one-third full (Figure 9-15) with their appropriate reagents.
- If both dampers are approximately one-half to one-third full, replace the flow cell cover and secure the captive screw. Be careful not to pinch the tubing.

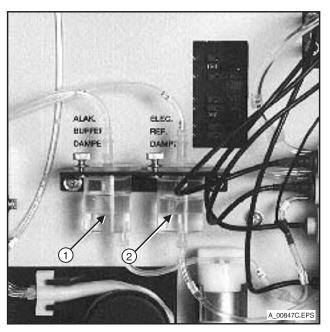
If one or both dampers are less than one-half to one-third full, proceed to step 4. If one or both dampers are more than one-half to one-third full, proceed to step 5.

- 4. If CO₂ Alkaline Buffer Damper assembly is less than half full, perform the following steps:
 - (a) Grasp input line #32 feeding into the damper assembly (Figure 9-16).
 - (b) Lift line slightly leaving the input straw extended into the damper assembly.

NOTE

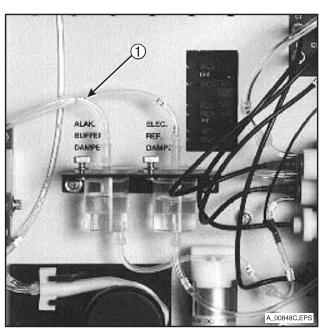
If the input straw is not extended into the damper, a reagent spill may occur in step (c) of this procedure.

(c) Prime alkaline buffer five times or as many times as necessary to fill the damper half full. Program as follows:



- 1 CO₂ Alkaline Buffer Damper
- 2 Electrolyte Reference Buffer Damper

Figure 9-15. Damper Assemblies



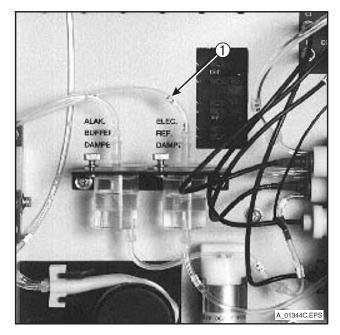
1 - Input Line #32

Figure 9-16. Damper Assemblies

- From the MASTER Screen, press F4 SPECIAL FUNC-TION.
- ii. Cursor and **SELECT** 1. Prime or type **1** and **ENTER**.
- iii. Cursor and **SELECT** Alkaline Buffer.
- iv. Press F1 START PRIME.
- v. Operator is prompted to enter the number of prime cycles. Type 5 and press ENTER. The display indicates the number of primes remaining.
- (d) Reconnect input line #32 to the damper as soon as the damper is one-half full. Allow prime cycles to be completed. The prime cycles are completed when System Status displays STANDBY.
- (e) If the Electrolyte Reference Damper is one-half full, reinstall the flow cell cover and secure the captive screw. Be careful not to pinch tubing.
- (f) Press **PREV SCREEN** to conclude this procedure.
- 5. If **Electrolyte Reference Damper** assembly is less than half full, perform the following steps:
 - (a) Grasp input line #33 feeding into the damper assembly (Figure 9-17).
 - (b) Lift line slightly, leaving only the input straw extended into the damper.

NOTE

If the input straw is not extended into the damper, a reagent spill may occur in step (c) of this procedure.



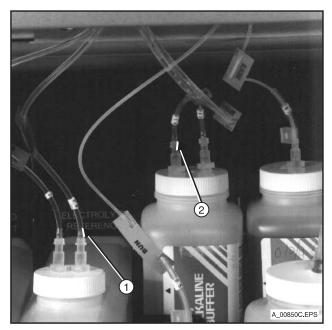
1 - Input Line #33

Figure 9-17. Damper Assemblies

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- (c) Prime electrolyte reference five times or as many times as necessary to fill the damper half full. Program as follows:
 - From the MASTER Screen, press F4 SPECIAL FUNC-TION.
 - ii. Cursor and **SELECT** 1. Prime or type **1** and **ENTER**.
 - iii. Cursor and **SELECT** Electrolyte Reference Flow Cell.
 - iv. Press F1 START PRIME.
 - v. Operator is prompted to enter the number of prime cycles. Type 5 and press ENTER. The display indicates the number of primes remaining.
- (d) Reconnect input line #33 to damper as soon as the damper is one-half full. Allow prime cycles to be completed. The prime cycles are completed when System Status displays STANDBY.
- (e) If the CO₂ alkaline buffer is onehalf full, reinstall the flow cell cover and secure the captive screw. Be careful not to pinch tubing.
- (f) Press **PREV SCREEN** to conclude this procedure.

- 6. If CO₂ Alkaline Buffer Damper assembly is more than one-half full, perform the following steps:
 - (a) Open CX3 reagent compartment door.
 - (b) Disconnect line #81 from the alkaline buffer reagent bottle (Figure 9-18).
 - (c) Prime alkaline buffer reagent three times. (Refer to step 4(c) for instructions.)
 - (d) Reconnect line #81 and prime alkaline buffer three additional times.
 - (e) Damper should now be approximately one-half full.
 - (f) If the Electrolyte Reference Damper is one-half full, reinstall the flow cell cover and secure the captive screw. Be careful not to pinch tubing.
 - (g) Press PREV SCREEN to conclude this procedure.
 - (h) Close compartment door.
- 7. If **Electrolyte Reference Damper** assembly is more than half full, perform the following steps:
 - (a) Disconnect line #83 (Figure 9-18) from the electrolyte reference reagent bottle.
 - (b) Prime electrolyte reference reagent (Electrolyte Reference Flow Cell) ten times. (Refer to step 5(c) for instructions.)
 - (c) Reconnect line #83 and prime electrolyte reference reagent 20 additional times.
 - (d) Damper should now be approximately one-half full.
 - (e) Reinstall the flow cell cover and secure the captive screw. Be careful not to pinch tubing.
 - (f) Press **PREV SCREEN** to conclude this procedure.
 - (g) Close compartment door.



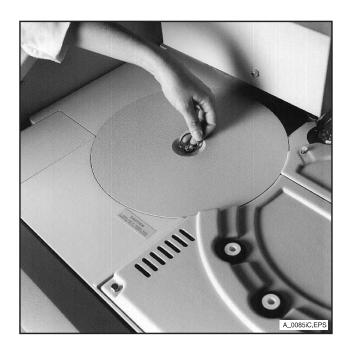
- 1 Line #81, CO₂ Alkaline Buffer
- 2 Line #83, Electrolyte Reference Buffer

Figure 9-18. CX3 Reagent Lines

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9.1.9 Clean CX3 Sample Pickup Probe (CX7 Users Only)

- 1. Prepare the system by removing the round, flat section of CX3 countertop (Figure 9-19A).
- 2. Program the system as follows:
 - (a) From the MASTER Screen, press **F4 SPECIAL FUNCTION**.
 - (b) Cursor and **SELECT** 6. Maintenance Procedures or type **6** and **ENTER**.
 - (c) Cursor and **SELECT** 5) CX3 Sample Probe Maintenance or type **5** and **ENTER**.
- The CX3 sample probe will rotate to a position that allows the operator easier access.
- 4. Insert the Sample Probe Cleaning Stylus (P/N 439606) from the CX3 maintenance kit, up through the bottom of the probe (Figure 9-19B). Move it up and down several times inside the full length of the probe to help remove protein build-up. After use, wipe the stylus with lintless tissue soaked in 70% isopropanol.



A. Prepare CX3 for Probe Cleaning

Figure 9-19. Cleaning CX3 Sample Pickup Probe

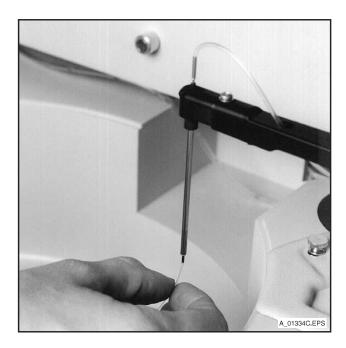
NOTE

If a clot is present in the sample probe, it may be necessary to insert the cleaning stylus from the top rather than from the bottom. Avoid inserting stylus from the top of the sample probe unless it is difficult to clean from the bottom. Frequent removal of probe tubing will cause tubing diameter to stretch, making it necessary to replace tubing. Stretched probe tubing could decrease instrument precision by allowing air into the sample channels.

CAUTION

Never use stylus in the CX4 probes. Teflon surface may be damaged.

- 5. Vigorously scrub the outside of the probe with lintless tissue moistened with 70% isopropanol.
- 6. Upon completion of the procedure, press **PREV SCREEN** to return the probe to the home position.
- 7. Replace the round, flat section of the CX3 countertop.



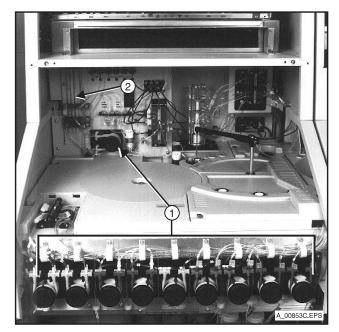
B. Insert Cleaning Stylus

Figure 9-19. Cleaning CX3 Sample Pickup Probe

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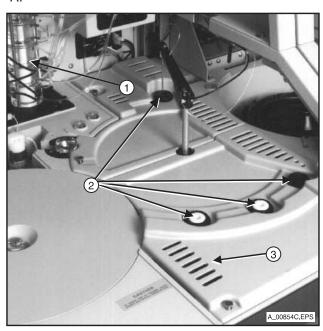
9.1.10 Prime CX3 Reagents; Observe Reagent Lines, Cups, Stirrers and Peri-pumps (CX7 Users Only)

- 1. Prime as follows:
 - (a) From the MASTER Screen, press **F4 SPECIAL FUNCTION**
 - (b) Cursor and SELECT 1. Prime or type 1 and ENTER.
 - (c) Cursor and **SELECT** all CX3 modules and chemistries.
 - (d) Press F1 START PRIME.
 - (e) Operator is prompted to enter the number of prime cycles. Type 10 and press ENTER. The display indicates the number of primes remaining.
- 2. While priming, observe for the following (Figure 9-20A and B):
 - (a) Inspect all reagent and drain lines for crimps, loose connections, leaks, or bubbles.
 - (b) Observe Peri-pumps are operating properly.
 - (c) Verify up/down movement of ratio pump.
 - (d) Verify that chemistry reaction cups are all filling, sipping and draining properly.
 - (e) Verify that magnetic stirrers are all stirring.
 - (f) Verify that creatinine and calcium module source lamps are on (inside of chemistry reaction cups).
 - (g) Observe red heater lamps through holes provided in chemistry reaction cup shield. Make sure that lamps are on, or intermittently on, indicating that preheater is functioning and that chemistry reaction cups have reached proper temperature.



- 1 Peri-numps
- 2 Reagent and Drain Lines

Α



- 1 Ratio Pum
- 2 Chemistry Reaction Cups, Magnetic Stirrers, Source Lamps
- 3 Heater Lamps

В.

Figure 9-20. Prime CX3 Reagents

NOTE

Additional priming may be required to remove any bubbles noted in the reagent or drain lines. If bubbles persist, aspirate out with a disposable transfer pipet.

- If any of the above are not functioning properly, refer to the following Paragraphs in the Diagnostics and Troubleshooting Guide:
 - (a) Refer to Section 3 for peri-pump troubleshooting.
 - (b) Refer to Section 3 for ratio pump troubleshooting.
 - (c) Refer to Section 3 for chemistry reaction cup troubleshooting.
 - (d) Refer to Section 3 for stirrer troubleshooting.
 - (e) Refer to Section 4 for source lamp troubleshooting.
 - (f) Refer to Section 4 for heater lamp troubleshooting.
- 4. Press **MASTER SCREEN** to conclude this procedure.

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9.2 WEEKLY MAINTENANCE PROCEDURES

CX4:

9.2.1 Internally Clean CX4 Sample and Reagent Pickup Probes

- 1. Pour 100 mL of a 10% dilution of Trace-Klean into a beaker.
- 2. Prepare the probes for maintenance as follows:
 - (a) From the MASTER Screen, press **F4 SPECIAL FUNCTION**.
 - (b) Cursor and **SELECT** 6. Maintenance Procedures or type **6** and **ENTER**.
 - (c) Cursor and **SELECT** 1). CX4 Sample Probe Maintenance or type **1** and then **ENTER**.
- 3. Disconnect the sample probe tubing from the top of the CX4 sample probe (Figure 9-21).
- 4. Connect the Probe Cleaner Tubing Assembly (P/N 759337) from the CX4 Maintenance Kit to the top of the sample probe assembly. Tighten no more than finger tight (Figure 9-22).

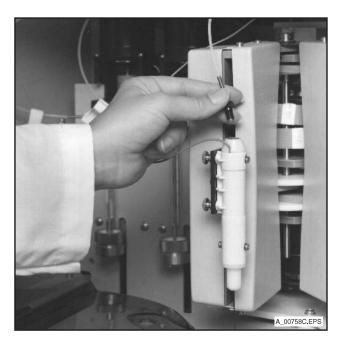


Figure 9-21. Disconnecting Sample Probe Tubing

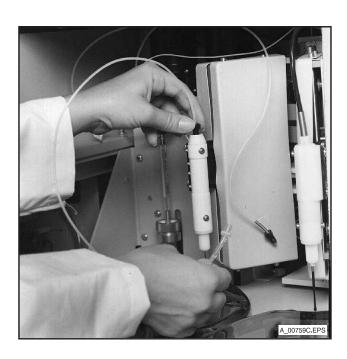


Figure 9-22. Connecting Probe Cleaner Tubing Assembly

- 5. Fill a 10-mL syringe with the diluted cleaning solution. Connect the syringe to the other end of the Probe Cleaning Assembly (Figure 9-22).
- Ensure the probe is positioned over wash cup. Dispense all of the syringe contents through the probe. Repeat until 50 mL has been dispensed.
- 7. Remove the cleaning assembly from the probe. Clean the probe tubing receptacle with a cotton swab wrapped in lintless tissue and moistened with deionized water. Dry with a cotton swab wrapped in lintless tissue (Figure 9-23).
- 8. Reconnect the probe tubing to the probe.
- 9. Repeat Steps 3 through 8 using the reagent probe.
- 10. Press **PREV SCREEN** to return probes to home state.
- 11. Prime the probes as follows:
 - (a) From the MASTER Screen, press the **F4 SPECIAL FUNC-TION** key.
 - (b) Move cursor to 1. Prime and press the **SELECT** key.
 - (c) Move cursor to Internal Probe Wash and press the SELECT key.
 - (d) Press the **F1 START PRIME** key.
- 12. Press **MASTER SCREEN** to conclude this procedure.

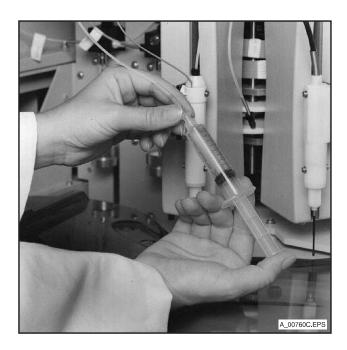


Figure 9-23. Connect Syringe to Probe Cleaning Assembly

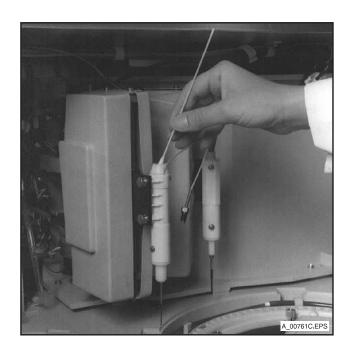


Figure 9-24. Probe Tubing Receptacle

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9.2.2 Clean/inspect In-line Filters at Peri-Pump Assemblies (CX7 Users Only)

- 1. Prevent the system from autopriming as follows:
 - (a) From the MASTER Screen, press **F4 SPECIAL FUNCTION**.
 - (b) Cursor and SELECT 6. Maintenance Procedures or type 6 and ENTER.
 - (c) Cursor and **SELECT** 9) CX3 Prevent Autoprime or type **9** and **ENTER**.
- Lower peri-pump cover. In-line filters are located at the alkaline buffer and electrolyte reference peri-pump assemblies.

NOTE

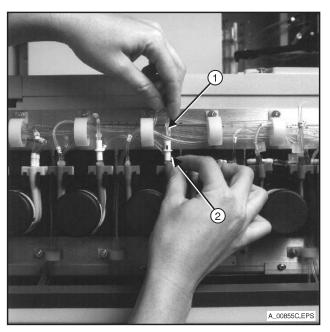
Change only one in-line filter at a time.

- 3. Remove reagent output (right) line from the top of the in-line filter.
- 4. Remove the in-line filter from the connector on the peri-pump tubing by gently twisting and pulling upward on the filter.
- 5. Inspect the in-line filter. If dirty, reverse flush with deionized water, or replace the filter (P/N 669212).

NOTE

When installing the in-line filter, be sure the arrow on the filter is pointing upward, the direction of reagent flow (Figure 9-25).

- After installation of the filter is complete, reattach the reagent output line to the top of the filter.
- 7. Repeat Steps 3 through 6 for the other filter.
- 8. Close peri-pump cover.
- 9. Press **PREV SCREEN** or **MASTER SCREEN** to conclude this procedure.



- 1 Output Line
- 2 Reagent Flow Arrow (up)

Figure 9-25. In-Line Filter

9.2.3 Adjust Pinch Valve Tubing (CX7 Users Only)

To prevent Cam pinch valve tubing from crimping, adjust tubing as follows:

9.2.3.1 E Cam Pinch Valve (Electrolyte) NOTE

There are two different models of pressure bars on the pinch valve assembly. The two different models are represented in Figures 9-26A and 9-26B. Please refer to the figure which represents the type of pressure bar on your instrument.

CAUTION

Never loosen both of the E Cam pinch valve pressure bars at the same time, as back-flushing may occur.

- 1. Access the E Cam Pinch Valve maintenance procedure as follows:
 - (a) From the MASTER Screen, press **F4 SPECIAL FUNCTION**.
 - (b) Cursor and **SELECT** 6. Maintenance Procedures or type **6** and **ENTER**.
 - (c) Cursor and SELECT 7) CX3 E Cam Maintenance or type 7 and ENTER. The system will respond with:

"Release upper pressure bar on valve 'E'".

Reposition and massage reagent tubing.

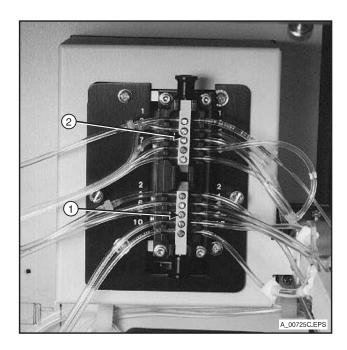
Replace upper bar and repeat procedure on lower bar.

Press **PREV SCREEN** to exit procedure.

CAUTION

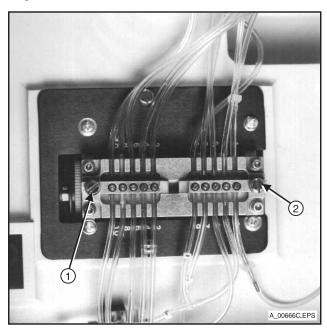
NEVER REMOVE BOTH BARS SIMULTANEOUSLY.

(d) Follow the procedure as described on screen.



Α

Figure 9-26. E Cam Pinch Valve



В

- 1 Controls Inlet Tube Lines
- 2 Controls Outlet Tube Lines

Figure 9-26. Pinch Valve Assembly

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- (e) When maintenance is completed, the system will rotate the E Cam pinch valve to position 3.
- (f) Proceed to Paragraph 9.2.3.2 for the C Cam pinch valve maintenance procedure.

9.2.3.2 C Cam Pinch Valve (Chemistry)

- Lower peri-pump cover and remove protective cover to expose the C Cam pinch valve (Figure 9-27).
- 2. C CAM PINCH VALVE LINES #124, #11, #12, #13, AND #14
 - (a) Locate lines #124, #11, #12, #13 and #14 on C Cam pinch valve (Figure 9-27).
 - (b) To loosen pressure bar, pull out on black pressure bar knob, or loosen the screws that hold down the pressure bar (Figure 9-25B), and gently lift bar upward.
 - (c) Carefully slide the pinch valve tubing (lines #124, #11, #12, #13 and #14) slightly to the right or left (without disconnecting the tubing manifold). Massage any crimps out of these tubing lines before securing the pressure bar.
 - (d) Locate line #124 and check for presence of Creatinine reagent or crystal formation inside the line. If either of these are present proceed to maintenance procedure 9.8.8 Cleaning C CAM Line #124.
 - (e) To secure pressure bar, pull out on black pressure bar knob and swing bar downward into position. Press in on black knob, locking it into place. Gently pull upward on black knob. If pressure bar is secure, it should not move. Repeat this step if bar is not securely in place. If your system has the other model type pinch valve assembly, tighten the screws that hold down the pressure bar (Figure 9-26B).
 - (f) Proceed to step 3.

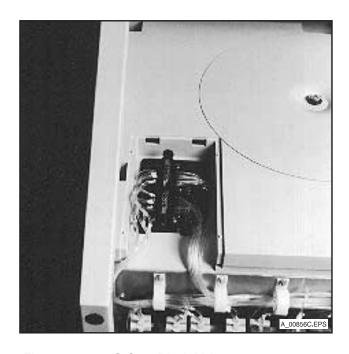
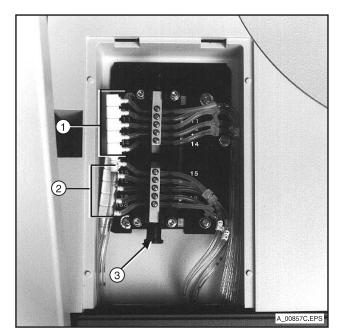


Figure 9-27. C Cam Pinch Valve

- 3. C CAM PINCH VALVE LINES #15, #16, #17, #18, AND #168
 - (a) Locate lines #15, #16, #17, #18 and #168 on C Cam pinch valve (Figure 9-28).
 - (b) To loosen pressure bar, pull out on black pressure bar knob, or loosen the screws that hold down the pressure bar (Figure 9-26B), and gently lift bar upward.
 - (c) Carefully slide the pinch valve tubing (lines #15, #16, #17, #18 and #168) slightly to the right or left (without disconnecting the tubing manifold). Massage any crimps out of these tubing lines before securing the pressure bar.
 - (d) To secure pressure bar, pull out on black pressure bar knob and swing bar downward into position. Press in on black knob, locking it into place. Gently pull upward on black knob. If pressure bar is secure, it should not move. Repeat this step if bar is not securely in place. If your system has the other model type assembly, tighten the screws that hold down the pressure bar (Figure 9-26B).
 - (e) Replace protective cover over C Cam pinch valve and close peripump cover.
 - (f) Proceed to Paragraph 9.2.3.3 for the Solenoid Pinch Valve Maintenance procedure.

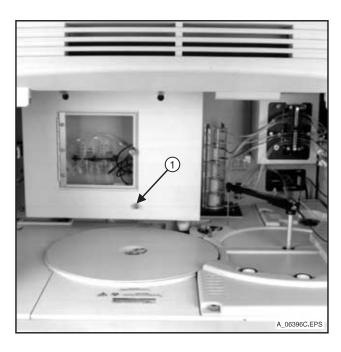
9.2.3.3 Adjust Solenoid Valve Tubing

- 1. Remove the flow cell cover as follows:
 - (a) Loosen the captive screw at the bottom of the flow cell cover (Figure 9-29).
 - (b) Grasp the flow cell cover.
 - (c) Carefully lift up and over the two fixed guide screws.
 - (d) Set the cover aside for later reinstallation.



- 1 Lines #124, #11, #12, #13, #14
- 2 Lines #15, #16, #17, #18, #168
- 3 Pressure Bar Knob

Figure 9-28. C Cam Pinch Valve



1 - Captive Screw

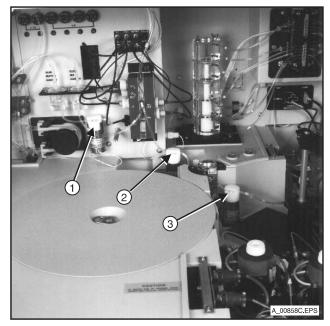
Figure 9-29. Removing Flow Cell Cover

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- 2. Remove both the front and rear shields over the chemistry reaction cups as follows:
 - (a) Unscrew all four retaining nuts and three thumb screws.
 - (b) Remove the front shield located over the BUN, glucose and calcium or total protein chemistry reaction cups.
 - (c) Program the system as follows:
 - From the MASTER Screen press F4 SPECIAL FUNC-TIONS.
 - ii. Cursor and SELECT 6. Maintenance Procedures or type 6 and ENTER.
 - iii. Cursor and SELECT 5) CX3 Sample Probe Maintenance or type 5 and ENTER. The sample probe arm will rotate away from the electrolyte injection cup.
 - (d) Remove the rear shield located over the creatinine chemistry reaction cup.
- 3. Locate the three discrete solenoid valves (Figure 9-30):
 - ALKALINE BUFFER SOLE-NOID VALVE. Located just below and to the right of the damper assemblies.
 - FLOW CELL SOLENOID VALVE. Located directly below the flow cell.
 - ELECTROLYTE INJECTION CUP SOLENOID VALVE. Located just to the right of and slightly below the electrolyte injection cup.

CAUTION

DO NOT pull tubing out of solenoid valves as backflow of reagent/waste may occur.



- 1 Alkaline Buffer Solenoid Valve
- 2 Flow Cell Solenoid Valve
- 3 Electrolyte Injection Cup Solenoid Valve

Figure 9-30. Location of Solenoid Valves

- Grasp the line on both sides of the solenoid and gently pull to the right or left to change the position of the tubing in the valve.
- Perform step 4 on all three solenoid valves.
- Replace rear shield over Creatinine reaction cup and secure retaining nuts and thumb screw.
- 7. Press **PREV SCREEN** to home probe.
- 8. Replace front shield over BUN, glucose, and calcium or total protein reaction cups. Secure retaining nuts and thumb screws.
- Replace cover over flow cell and secure captive screw. Be careful not to pinch the tubing.

9.2.3.4 Check C Cam Pinch Valve Vent Line #124

- 1. Lower peri-pump cover and remove protective cover to expose the C Cam pinch valve (Refer to Figure 9-27).
- Locate line #124 and check for presence of Creatinine reagent or crystal formation. If either of these are present proceed to maintenance procedure 9.8.8 Cleaning C CAM Line #124.
- 3. If line is clean, replace C Cam protective cover and close peri-pump cover.

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9.2.4 Clean Calcium Chemistry Reaction Cup and Stirrer with Bleach (CX7 Users Only)

The calcium reaction cup and stirrer should be cleaned weekly or if a successful calibration cannot be achieved.

NOTE

If the average number of samples analyzed is greater than 125 per day, or if a lot of PLASMA samples are analyzed, this procedure may need to be done more frequently.

- A fresh 10% bleach solution will be used in this procedure to clean the calcium chemistry reaction cup. To prepare this solution, mix one part of bleach with nine parts of deionized water.
- 2. Using a disposable transfer pipet, aspirate the calcium reagent out of the calcium chemistry reaction cup.
- 3. Using a disposable transfer pipet, fill the calcium reaction cup with the diluted bleach solution to a level approximately 1/4 inch (6 mm) above the sip hole.
- Allow the calcium cup to stand idle for three minutes.
- Using a transfer pipet, aspirate the bleach from the calcium cup and discard.
- Carefully extract the stirrer using the stirrer removal tool.

NOTE

Stirrers must never be interchanged from one reaction cup to another, as contamination may occur.

- 7. Clean the stirrer using lintless tissue dampened with 10% bleach solution.
- 8. Using two or three cotton tipped applicators saturated with 10% bleach, wipe the inside of the reaction cup.
- 9. Re-install stirrer in reaction cup.

- 10. Prime the calcium module five times as follows:
 - (a) From the MASTER Screen, press **F4 SPECIAL FUNCTION**.
 - (b) Cursor and **SELECT** 1. Prime or type **1** and **ENTER**.
 - (c) Cursor and **SELECT** CA3.
 - (d) Press F1 START PRIME.
 - (e) Operator is prompted to enter the number of prime cycles. Type 5 and press ENTER. The display indicates the number of primes remaining.
- 11. While module is priming, observe lines and chemistry reaction cup to determine there are no leaks. Stop the priming if any leaks are noticed and correct the problem.
- 12. Observe stirrer to verify that it is rotating properly.
- 13. Verify that there are no bubbles or loose fibers in the calcium chemistry reaction cup. If bubbles or fibers are present, aspirate them out with a transfer pipet. Prime channel three times or until bubbles have disappeared (refer to step 10).

This completes the bleaching of the calcium chemistry reaction cup and stirrer.

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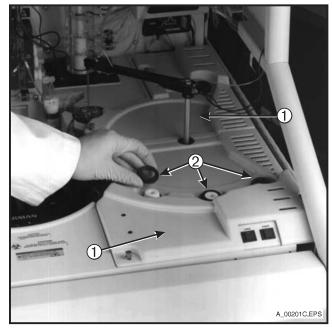
9.3 TWO-WEEK MAINTENANCE PROCEDURES CX3:

9.3.1 Clean Total Protein Reaction Cup, Lines, and Stirrer (CX7 DELTA Users Only)

The total protein reaction cup and stirrer should be cleaned every two weeks or if a successful calibration using the SYNCHRON CX Protein Calibrators cannot be achieved.

To clean the total protein reaction cup and stirrer, proceed as follows:

- Remove reagent straw from the total protein reagent and place the straw in a container of 1% HCl solution.
- Perform a reagent load for total protein. Allow cleaning solution to remain in cup for five minutes.
- Remove reagent straw from 1% HCI solution and place the straw into a beaker containing deionized water.
- 4. Perform a reagent load for total protein (TP3).
- 5. Remove reagent straw from water and place the straw into the total protein (TP3) reagent bottle.
- Perform a reagent load for total protein.
- Use the Adjust Volumes function in Reagent Load (paragraph 6.2.3 of the Operating Instructions Manual) to match the current reagent level in the total protein bottle.
- Unscrew front three retaining nuts and retaining screw (Figure 9-31) and remove the chemistry cup shield located over the BUN, glucose, and calcium or total protein reaction cups.
- 9. Prepare reaction cup for maintenance. Program system as follows:
 - (a) From the Special Function Screen, cursor and SELECT 6.
 Maintenance Procedures or type 6 and ENTER.



- 1 Chemistry Cup Shields
- 2 Retaining Nut

Figure 9-31. Removal/Replacement of Chemistry Cup Shield

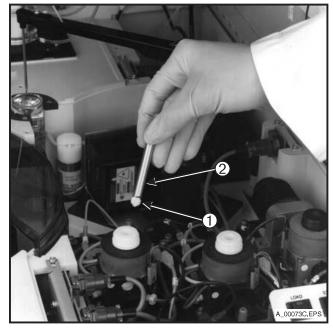
- (b) From the Maintenance Procedures Screen, cursor and SELECT 6. Chemistry Maintenance or type 6 and ENTER.
- (c) Cursor and SELECT TP3 and press F1 Continue. The cup is drained of reagent and ready for maintenance.
- 10. Unscrew retainer nut and partially withdraw photodetector assembly from reaction cup (Figure 9-33).
- 11. Without scratching lamp or detector lens carefully extract stirrer using Stirrer Removal Tool (Figure 9-32).
- 12. Clean blue stirrer using lintless tissue dampened in 1% HCI.
- 13. Using cotton-tipped applicators saturated with 1% HCI and rolled between finger tips, wipe inside of cup. Rolling the applicator tip compacts the cotton and reduces the possibility of leaving loose fibers in the cup.

CAUTION

Stirrers must never be interchanged from one reaction cup to another, as contamination may occur.

- 14. Reinstall blue stirrer in reaction cup by placing stirrer (flat side up) on Stirrer Removal Tool (Figure 9-32). Lower stirrer to bottom of cup. To dislodge stirrer, twirl and rapidly lift removal tool. Tap stirrer with nonmagnetic end of tool to position stirrer at bottom of cup.
- 15. Finger-tighten photodetector assembly retainer nut.
- 16. Prime the total protein module five times. Program system as follows:
 - (a) From the Special Function Screen, **SELECT** 1. PRIME and **ENTER** or type **1** and **ENTER**.
 - (b) **SELECT** TP3 and **ENTER**. System responds with:

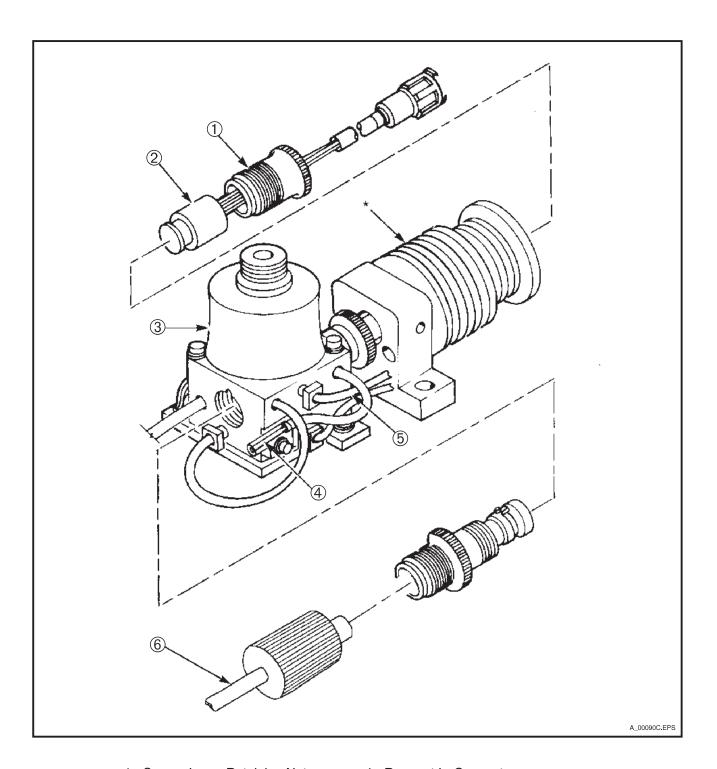
CX3 Prime Cycles:



- 1 Stirrer
- 2 Stirrer Removal Tool

Figure 9-32. Removing/Installing Stirrer in Reaction Cup

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- 1 Source Lamp Retaining Nut
- 2 Source Lamp Assembly
- 3 Reagent Preheater
- 4 Reagent In-Connector
- 5 Sip Line
- 6 Photodetector Assembly

*CAUTION

DO NOT disassemble this portion of optical system as misalignment could result.

Figure 9-33. Total Protein Reaction Cup Assembly

- (c) Type 5 and ENTER. The Prime Screen indicates the number of primes remaining. The prime cycles are completed when the System Status displays Standby.
- 17. While module is priming, observe lines and reaction cup to determine there are no leaks. Stop the priming if any leaks are noticed and correct the problem.
- 18. Observe stirrer to verify that it is rotating properly.
- 19. Verify that there are no bubbles or loose fibers in the total protein reaction cup. If bubbles or fibers are present, aspirate them out with a transfer pipet and prime three times or until bubbles have disappeared.

NOTE

If additional chemistry reaction cup maintenance procedures are to be performed, proceed to Step 1 of the appropriate procedire. If this is the only chemistry reaction cup procedure being performed, proceed to Step 20 of this procedure.

- 20. Carefully place chemistry cup shield over reaction cups. Do not pinch wires and tubes.
- 21. Finger tighten the three retaining nuts and retaining screw on top of chemistry cup shield (Figure 9-31).

This completes the cleaning of the total protein reaction cup and stirrer.

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9.3.2 Recharge Glucose Electrode and Clean Chemistry Reaction Cup Lines and Stirrer (CX7 Users Only)

The glucose chemistry reaction cup and stirrer should be cleaned every two weeks or if a successful calibration, using the SYNCHRON CX Calibration Standards cannot be achieved. Plan to allow 30 minutes for the electrode to achieve temperature stability following this procedure. Recharge the glucose electrode and clean the chemistry reaction cup and stirrer as follows:

- 1. Open CX3 reagent compartment door.
- Remove reagent straw from the glucose reagent and place the straw in a beaker of warm DI water.
- 3. Perform a reagent load for glucose.
- 4. Prime the GLU3 module 10 times.
- Remove reagent straw from the water and put the straw into the glucose reagent bottle.
- 6. Perform a reagent load for glucose.
- 7. Use the Adjust volume function in Reagent Load (Paragraph 6.2.3) to match the current reagent level in the glucose bottle.
- Remove the front shield over the BUN, glucose and calcium or total protein chemistry reaction cups as follows:
 - (a) Unscrew and remove the three retaining nuts and one thumb screw (Refer to Figure 9-31).
 - (b) Gently lift shield off.
- 9. Prepare chemistry reaction cup for maintenance as follows:
 - (a) From the MASTER Screen, press F4 SPECIAL FUNC-TIONS.
 - (b) Cursor and SELECT 6. Maintenance Procedures or type 6 and ENTER.

- (c) Cursor and **SELECT** 6. CX3 Chemistry Maintenance or type **6** and **ENTER**.
- (d) Cursor and SELECT GLU3.
- (e) Press F1 CONTINUE. This will drain the cup of reagent so that maintenance may be performed.
- Disconnect red and black glucose pin leads from connector panel (Figure 9-34).
- Unscrew glucose electrode retainer nut and withdraw electrode- assembly from chemistry reaction cup (Figure 9-35). Set electrode-assembly aside for later cleaning.

CAUTION

Always remove electrode (step 11) before removing stirrer (step 12). This prevents possible damage to the delicate electrode tip.

- 12. Extract stirrer using Stirrer Removal Tool (Refer to Figure 9-32).
- 13. Clean white stirrer using lintless tissue dampened in 70% isopropanol.

CAUTION

Stirrers must never be interchanged from one chemistry reaction cup to another, as contamination may occur.

- 14. Carefully wipe inside of chemistry reaction cup with cotton-tipped applicators saturated with 70% isopropanol and rolled between finger tips. Rolling the applicator tip compacts the cotton and reduces the possibility of leaving loose fibers in the cup.
- 15. Using lintless tissue saturated with 70% isopropanol, clean mounting port for electrode.

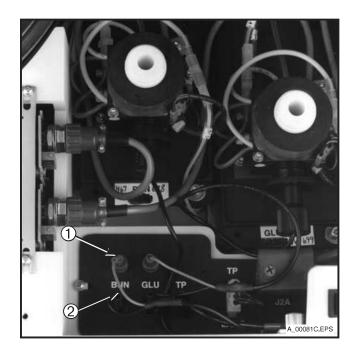
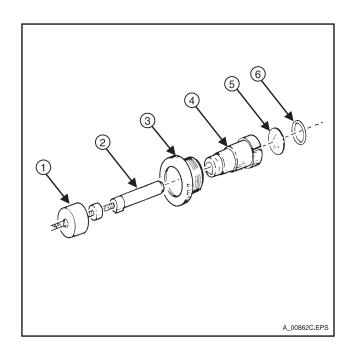


Figure 9-34. Glucose Pin Leads



- 1 Electrode Cap Nut
- 2 Electrode
- 3 Retainer Nut
- 4 Electrode Retainer
- 5 Membrane
- 6 O-Ring

Figure 9-35. Glucose Electrode

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- 16. Using dry, lintless tissue, wipe electrode mounting port.
- 17. Reinstall white stirrer in chemistry reaction cup as follows:
 - (a) Place white stirrer (flat side up) on Stirrer Removal Tool.
 - (b) Lower stirrer to bottom of cup.
 - (c) Dislodge stirrer by twirling and rapidly lifting removal tool. Stirrer will remain in cup.
- 18. Recharge electrode as follows:
 - (a) Unscrew electrode cap nut and withdraw electrode from retainer. Set retainer nut aside for later reinstallation.
 - (b) Remove O-ring and membrane from end of retainer. Discard membrane.
 - (c) Rinse retainer and O-ring in deionized water and dry with lintless tissue.
 - (d) Place O-ring on sheet of lintless paper.
 - (e) Place new membrane (make sure there is only one) on top of O-ring and center. Avoid contacting membrane with fingers.

NOTE

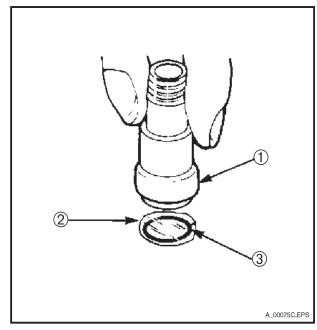
Always discard paper disk that separates new membranes.

(f) Push electrode retainer onto O-ring (Figure 9-36). Check membrane for proper seating: no wrinkles or tears in the membrane appearance.

CAUTION

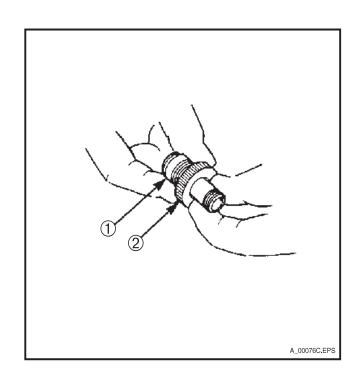
Do not seat membrane on retainer with twisting motion as retainer could slice membrane.

- (g) Place retainer nut on retainer and set aside for later use (Figure 9-37).
- (h) Wipe old gel from face of electrode and rinse electrode body thoroughly in deionized water. Wipe circular silver anode firmly with clean, moistened tissue and use edge of fingernail to remove oxidation products. The wooden end of an applicator stick may also be used, but do NOT use a needle or any other metal object.



- 1 Retainer
- 2 Membrane
- 3 O-ring

Figure 9-36.



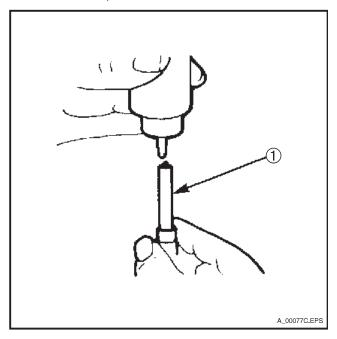
- 1 Retainer
- 2 Electrode Retainer Nut

Figure 9-37.

CAUTION

Never rinse electrode in alcohol, as damage to the electrode may result.

- (i) Wipe electrode dry.
- (j) Apply liberal amount of gel to tip of electrode, then wipe away to condition electrode glass for fresh charge of gel (Figure 9-38).



1 - Electrode

Figure 9-38.

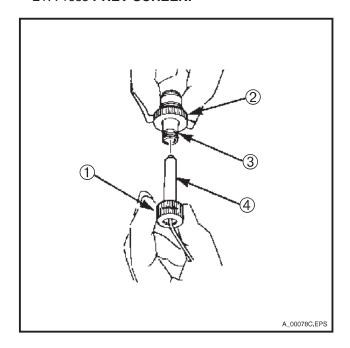
- (k) Apply fresh gel to electrode tip, to a depth of 1/16 to 1/8 inch (1.59 to 3.18 mm). Cover entire tip of electrode, being careful not to leave air bubbles.
- 19. Reinstall the glucose electrode as follows:

CAUTION

DO NOT over tighten electrode cap nut (Step 19a) as membrane and O-ring can be pushed off the end of the retainer.

(a) Align key on electrode with keyway in retainer. Carefully insert electrode into retainer. Finger tighten electrode cap nut (Figure 9-39).

- (b) Align key on electrode-retainer assembly with keyway on electrode port and fingertighten in place with retainer nut.
- 20. Reconnect red and black glucose plugs into connector panel (Refer to Figure 9-34).
- 21. Press PREV SCREEN.



- 1 Retainer Nut
- 2 Electrode Retainer Nut
- 3 Retainer
- 4 Electrode

Figure 9-39.

- 22. Prime as follows:
 - (a) From the MASTER Screen, press **F4 SPECIAL FUNCTION.**
 - (b) Cursor and SELECT 1. Prime or type 1 and ENTER.
 - (c) Cursor and SELECT GLU3.
 - (d) Press F1 START PRIME.
 - (e) Operator is prompted to enter the number of prime cycles. Type 15 and press ENTER. The display indicates the number of primes remaining.
- 23. While module is priming, observe lines and chemistry reaction cup to determine there are no leaks. Stop the priming if any leaks are noticed and correct the problem.
- 24. Observe stirrer to verify that it is rotating properly.

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NOTE

If additional chemistry reaction cup maintenance procedures are to be performed, proceed to step 1 of the appropriate procedure. If this is the only chemistry reaction cup maintenance procedure being performed, proceed to step 25 of this procedure.

- 25. Carefully place shield over chemistry reaction cups. Take care that wires and tubes are not pinched under edges of cover.
- 26. Replace and secure the three retaining nuts and one thumb screw on the shield.
- 27. Close compartment door.

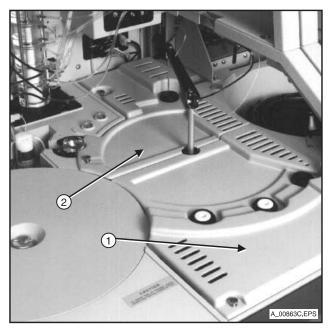
This completes the recharging of the glucose electrode and cleaning of the chemistry reaction cup and stirrer. Allow 30 minutes for temperature stability before calibration and operation of this module.

9.3.3 Clean Creatinine Chemistry Reaction Cup and Stirrer (CX7 Users Only)

The creatinine chemistry reaction cup and stirrer should be cleaned every two weeks or if calibration, using the SYNCHRON CX Calibration Standards, cannot be achieved.

Clean the creatinine chemistry reaction cup and stirrer as follows:

- 1. Remove both the front and rear shields (Figure 9-40) over the chemistry reaction cups as follows:
 - (a) Unscrew all four retaining nuts and three thumb screws.
 - (b) Remove the front shield located over the BUN, glucose and calcium or total protein chemistry reaction cups.
 - (c) Program the system as follows:
 - From the MASTER Screen, press F4 SPECIAL FUNC-TIONS.
 - ii. Cursor and SELECT 6. Maintenance Procedures or type 6 and ENTER.
 - iii. Cursor and SELECT 5. CX3 Sample Probe Maintenance or type 5 and ENTER. The sample probe arm will rotate away from the electrolyte injection cup.
 - iv. Remove the rear shield located over the creatinine chemistry reaction cup.
 - v. Press **PREV SCREEN** to home probe.
- 2. Prepare chemistry reaction cup for maintenance as follows:
 - (a) From the Special Functions Screen, cursor and SELECT 6. Maintenance Procedures or type 6 and ENTER.
 - (b) Cursor and **SELECT** 6. CX3 Chemistry Maintenance or type **6** and **ENTER**.
 - (c) Cursor and SELECT CRE3.
 - (d) Press F1 CONTINUE. This will drain the cup of reagent so that maintenance may be performed.

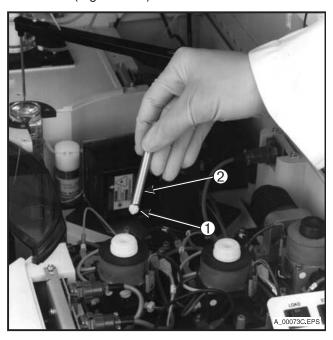


- 1 Front Shield
- 2 Rear Shield

Figure 9-40. Removing Chemistry Shields

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- 3. Unscrew retainer nut and partially withdraw photodetector assembly from reaction cup. (Figure 9-42).
- 4. Without scratching lamp or detector lens, carefully extract blue stirrer using Stirrer Removal Tool (Figure 9-41).



- 1 Stirrer
- 2 Stirrer Removal Tool

Figure 9-41.

5. Clean blue stirrer using lintless tissue dampened with deionized $\rm H_2O$.

CAUTION

Stirrers must never be interchanged from one chemistry reaction cup to another, as contamination may occur.

- Carefully wipe inside of cup with cotton-tipped applicators saturated with deionized H₂O and rolled between finger tips. Rolling applicator tip compacts the cotton and reduces the possibility of leaving loose fibers in the cup.
- 7. Reinstal blue stirrer in chemistry reaction cup as follows:
 - (a) Place stirrer (flat side up) on Stirrer Removal Tool.
 - (b) Lower stirrer to bottom of cup.
 - (c) Dislodge stirrer by twirling and rapidly lifting removal tool. Stirrer will remain in cup.

- Finger-tighten photodetector assembly retainer nut.
- 9. Press PREV SCREEN.
- 10. Prime as follows:
 - (a) From the MASTER Screen, press **F4 SPECIAL FUNCTION**.
 - (b) Cursor and SELECT 1. Prime or type 1 and ENTER.
 - (c) Cursor and SELECT CRE3.
 - (d) Press F1 START PRIME.
 - (e) Operator is prompted to enter the number of prime cycles. Type 3 and press ENTER. The display indicates the number of primes remaining.
- 11. While module is priming, observe lines and chemistry reaction cup to determine there are no leaks. Stop the priming if any leaks are noticed and correct the problem.
- 12. Observe stirrer to verify that it is rotating properly.
- 13. Verify that there are no bubbles or loose fibers in the creatinine chemistry reaction cup. If bubbles or fibers are present, aspirate them out with a transfer pipet.

NOTE

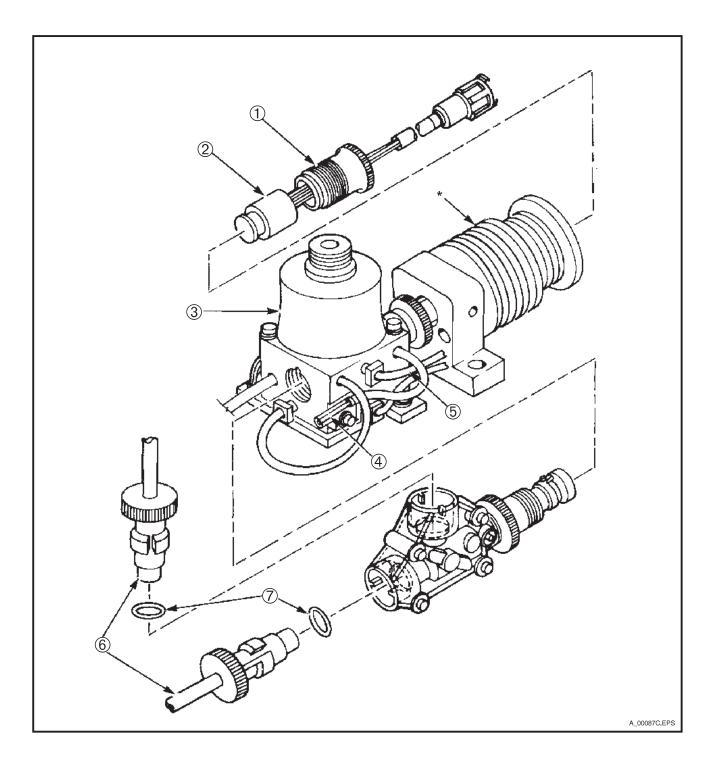
If additional chemistry reaction cup maintenance procedures are to be performed, proceed to step 1 of the appropriate procedure. If this is the only chemistry reaction cup maintenance procedure being performed, proceed to step 14 of this procedure.

- 14. Replace both shields over the chemistry reaction cups as follows:
 - (a) Program the system as follows:
 - i. From the MASTER Screen, press **F4 SPECIAL FUNCTIONS.**
 - ii. Cursor and **SELECT** 6. Maintenance Procedures or type **6** and **ENTER**.
 - iii. Cursor and SELECT 5. CX3 Sample Probe Maintenance or type 5 and ENTER. The sample probe arm will rotate away from the electrolyte injection cup.

- iv. Replace the rear shield. Take care that wires and tubes are not pinched under edges of cover.
- v. Press **PREV SCREEN** to home probe.
- (b) Replace the front shield over the BUN, glucose and calcium or total protein chemistry reaction cups. Take care that wires and tubes are not pinched under edges of cover.
- (c) Replace and secure all four retaining nuts and three thumb screws.

This completes the cleaning of the creatinine chemistry reaction cup and stirrer.

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- 1 Source Lamp Retaining Nut
- 2 Source Lamp Assembly
- 3 Reagent Preheater
- 4 Reagent In-Connector
- 5 Sip Line
- 6 Photodetector Assembly
- 7 O-ring

*CAUTION

DO NOT disassemble this portion of optical system as misalignment could result.

Figure 9-42. Creatinine Reaction Cup Assembly

9.3.4 Clean Flow Cell With Bleach (CX7 Users Only)

The following Flow Cell Cleaning procedure should be performed every two weeks if the average number of electrolyte samples analyzed daily is less than 350; if the average number of electrolyte samples analyzed daily is greater than 350, the Flow Cell Cleaning procedure should be performed every week.

NOTE

If electrolyte calibration has timed out, it MUST be extended in order to proceed with the Flow Cell Cleaning procedure. It is not necessary to remove the chloride electrode when performing the Flow Cell Cleaning procedure.

- Prepare a fresh 2.6% dilution of hypochlorite as follows:
 - (a) If a preparation of 5.25% sodium hypochlorite is available as household bleach then a 2.6% dilution is made by mixing one part of household bleach with one part deionized water.
 - (b) Other sodium hypochlorite solutions should be diluted with water to obtain a 2.6% dilution.
- 2. Program the system for five (5) cups of potassium as follows:
 - (a) From the MASTER Screen, press **F1 SAMPLE PROGRAM**.
 - (b) From the SAMPLE PROGRAM Screen, press **F1 PROGRAM SECTORS**.
 - (c) Select sector number to be programmed and press **ENTER**.
 - (d) Enter the Sample ID.
 - (e) Select potassium (K) as desired test.
 - (f) Press **F7 NEXT AVL** or **F8 NEXT CUP** to continue programming four (4) more cups.
 - (g) When all programming is complete, press PREV SCREEN.

NOTE

If programming samples in the bar code mode, use the manual cup assignment option (section 6.4.2.3).

- 3. Place the fresh 2.6% dilution of hypochlorite into the five (5) sample cups and load the samples on the system.
- 4. Press the START key.

NOTE

Ignore the results for these samples; the results may be flagged as "Results Suppressed".

- 5. When CX7 system stops, flush the flowcell of residual hypochlorite as follows:
 - (a) From the MASTER Screen, press F4 SPECIAL FUNCTION.
 - (b) Cursor and SELECT 1. Prime or type 1 and ENTER.
 - (c) Cursor and **SELECT** Ratio Pump.
 - (d) Press F1 START PRIME.
 - (e) Operator is prompted to enter the number of prime cycles. Type 10 and press ENTER. The display indicates the number of primes remaining.
- 6. Calibrate the electrolytes and run controls to verify acceptable instrument operation.

After completion of all steps the system is ready for use.

NOTE

It is recommended that the Chloride Electrode Maintenance procedure be done every two months or whenever the Enzymatic Flow Cell Cleaning procedure is done. Perform the Enzymatic Flow Cell Cleaning procedure when a yellow discoloration at or above the CO₂ acid port is visible. Refer to Section 9.8.12 for a detailed description of the enzyme cleaning procedure.

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CX4:

9.4.1 Check for Proper Operation of Refrigerator Circulation Fan and for Condensation or Ice Buildup

- Access the REAGENT LOAD Screen as follows:
 - (a) From the MASTER Screen, press **F2 REAGENT LOAD**.
 - (b) Cursor and **SELECT** an empty cartridge position.

NOTE

It may be necessary to remove a reagent cartridge to complete this step.

- (c) Press F1 AUTO LOAD.
- 2. Wait for system prompt, then lift the reagent carousel door (Figure 9-43).
- Look into the refrigerator and observe for excessive condensation (pooling of water at edge of reagent cartridge compartment) on the bottom of the carousel or for ice formation. If no condensation or ice is found, proceed to step 4 (Figure 9-44).

If condensation or ice is found, proceed as follows:

- (a) Verify proper Peltier temperature from F8 SYSTEM PARAME-TERS, then F7 STATUS MONI-TOR.
- (b) If temperature is incorrect, refer to the Diagnostics and Troubleshooting Guide (Section 3.4).
- (c) If temperature is correct, remove any ice and dry any excess condensation by wiping with lintless cloth. Proceed to step 4.
- Verify proper operation of the circulation fan:
 - (a) Open reagent compartment door.

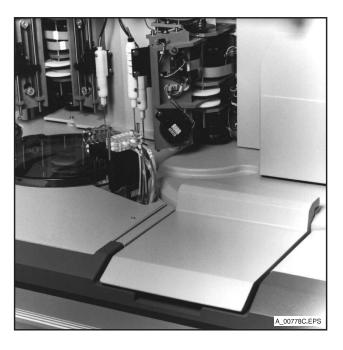


Figure 9-43. Reagent Carousel Door

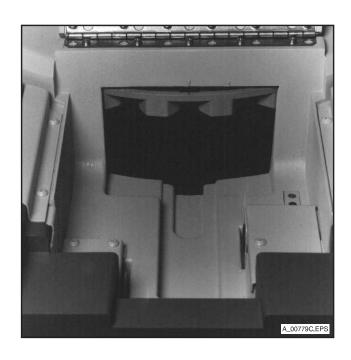


Figure 9-44. Refrigerator

(b) Place fingertips inside the reagent compartment. Verify flow of cool air.

If fan is operating properly, proceed to step 5. If fan is not operating properly, call your local Beckman Office for assistance (North American Customers call 1-800-854-3633).

5. Replace any reagent cartridge (if previously removed).

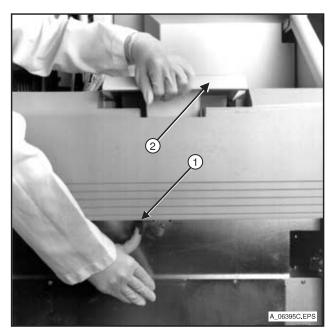
NOTE

If procedure 9.4.2 is to be performed at this time, go to step 3 of next procedure. If only this maintenance procedure is to be performed at this time, proceed to step 6.

6. Close the reagent carousel door.

9.4.2 Clean the Reagent Bar Code Reader Window

- 1. Open the right lower compartment door.
- 2. Push the red CX4 reagent door release lever to the right and lift up the reagent door (Figure 9-45).



- 1 Release Lever
- 2 Reagent Door

Figure 9-45. Reagent Door Release Lever

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- Clean the bar code reader window (Figure 9-46) with a mild detergent solution. Rinse with deionized water. Wipe dry with clean lintless cloth.
- 2. Close the reagent door and secure release lever.
- 3. Close the right lower compartment door.

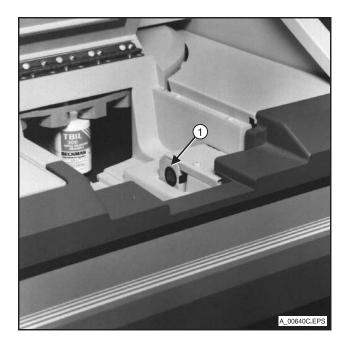


Figure 9-46. Reagent Bar Code Reader Window

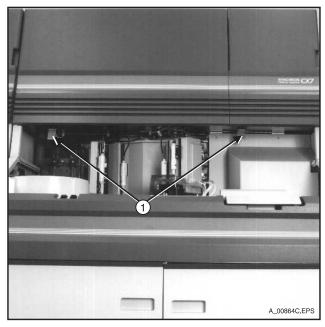
9.4.3 Clean the CX4 Electronics Compartment, Refrigerator and Power Supply Air Filters

NOTE

Instructions for cleaning the electronics compartment filter (Steps 1-3) apply only to CX4 systems. Some CX4CE and all CX4 DELTA systems do not have an electronics compartment filter.

To minimize system down time, it is recommended that you have a clean CX4 refrigerator air filter (P/N 759403 or P/N 756961) and power supply air filter (P/N 759070) on hand. This would allow you to install the clean filters and clean the dirty filters at your convenience.

- 1. Lift the CX4 electronics compartment cover as follows:
 - (a) Pull down on and release both lid latches located under front of main compartment cover (Figure 9-47).



1 - Lid Latches

Figure 9-47. Releasing Lid Latches, Main Electronics Compartment

(b) Lift cover upward until lid support latches lock. After support latches lock, slowly lower cover until it is supported by the latch mechanism. The cover will be supported approximately parallel with the top plane of the instrument.

CAUTION

Do not place anything on the compartment cover while it is in the open position. Do not lean on or put pressure on the cover while it is in the open position.

- Lift hinged access door (Figure 9-48).
 If the card-cage cover has no hinged access door, refer to the Diagnostics and Troubleshooting Guide (Section 4.4) for procedure to remove card-cage cover.
- 3. Pull out the CX4 electronics compartment air filter (P/N 759020) located to the right of the circuit boards (Figure 9-49). Set aside for cleaning.



Figure 9-48. Hinged Access Door

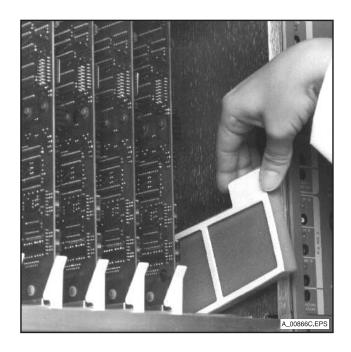


Figure 9-49. Electronics Compartment Air Filter

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NOTE

Some CX4CE and CX7 Systems may be fitted with refrigerator air filters which resemble the one pictured in Figure 9-50 (P/N 759403).

Other CX4CE, CX7 Systems, and all CX4 DELTA and CX7 DELTA systems may be fitted with refrigerator air filters which resemble the one pictured in Figure 9-51C (P/N 756961).

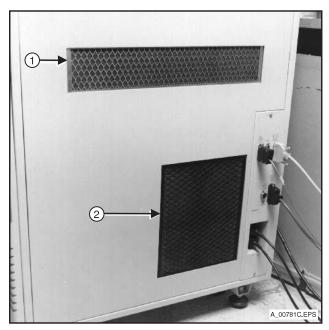
 Locate the refrigerator (P/N 759403 or 756961) and power supply (P/N 759070) air filters on the right side of the instrument (Figure 9-50).

NOTE

Some systems have the fan noise muffler update installed; operators of these systems should proceed to Step 5. For systems without the update, proceed with Step 6.

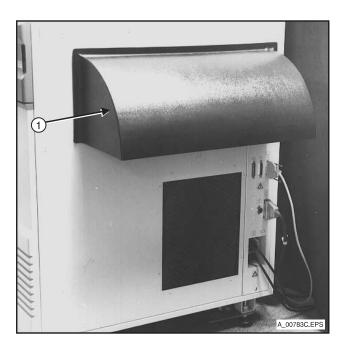
For systems with fan noise muffler:

- 5. Locate the fan noise muffler on the right side of the system (Figure 9-51A).
 - (a) Gently pull the muffler up and away from the system.
 - (b) Locate the refrigerator (P/N 759403 or 756961) and the power supply (P/N 759070) filters on the right side of the instrument.
- Lift each filter up and pull out from the bottom (Figure 9-51B) or remove refrigerator fan filter (top) by grasping the edge closest to the front of the instrument and pulling the filter out towards the front (Figure 9-51C).



- 1 Refrigerator Air Filter
- 2 Power Supply Air Filter

Figure 9-50. Filter Locations



Α

1 - Fan Noise Muffler

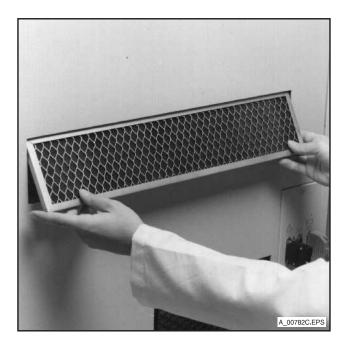
Figure 9-51. Locating Noise Fan Muffler

 Vacuum or brush each filter thoroughly to remove dust. If excessively dirty, rinse with deionized water. Vigorously shake residual water from filters. Allow the filters to air dry completely.

CAUTION

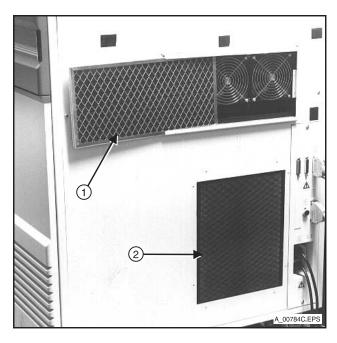
DO NOT place a damp filter back on the system. Residual moisture may cause damage to the system.

- 8. Replace each filter.
- Close hinged access door on cardcage cover.
- 10. Close electronic compartment cover as follows:
 - (a) Push cover up slightly and HOLD up.
 - (b) While supporting the cover, push down on the support latch lever and hold.
 - (c) Slowly lower cover while holding support latch down. Release support latch after cover gets below locking position. Continue to lower cover slowly to normal locked position.
 - (d) Lock cover in place with lid latches.
- 11. If necessary, reattach fan noise muffler to the right side of the instrument.



В

Figure 9-51. Removing Filters



С

- 1 Refrigerator Fan Filter (Partially Removed)
- 2 Power Supply Fan Filter

Figure 9-51. Removing Refrigerator Fan Filter

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9.4.4 Replace Probe Rinse Solution In-line Filter

- Open the lower middle (left) compartment door.
- 2. Turn off the hydropneumatic system as follows:
 - (a) From the MASTER Screen, press **F4 SPECIAL FUNCTION**.
 - (b) Cursor and **SELECT** 6. Maintenance Procedures or type **6** and **ENTER**.
 - (c) Cursor and **SELECT** 4. CX4 Hydropneumatic System Shutdown or type **4** and **ENTER**.

NOTE

To release residual pressure, loosen the cap on the Probe Rinse bottle. Always wear eye protection and rubber gloves when performing this procedure. Re-tighten immediately.

- 3. Disconnect the tubing from both sides of the probe rinse in-line filter (Figure 9-52).
- 4. When replacing filter, twist connections firmly.
- 5. Press PREV SCREEN to conclude procedure.
- 6. Close compartment door.



Figure 9-52. Probe Rinse Solution In-Line Filter (P/N 448658)

9.4.5 Clean Sample Bar Code Reader Window

WARNING

DO NOT TAMPER WITH OR REMOVE HOUSING OF SAMPLE BAR CODE READER. THE SAMPLE BAR CODE READER IS A CLASS II MOVING BEAM SCANNER.

- 1. Wait until system status reads "Standby".
- 2. Remove any sectors present on system.
- Clean the sample bar code reader window with a mild detergent solution, rinse with deionized water, and wipe dry with lintless cloth (Figure 9-53).
- 4. Verify correct placement of bar code reader window in slot. If the system contains a separate <u>sector</u> reader (CX4CE/CX7 systems), the sample bar code reader window must be oriented with the hole in the top right corner.

If the system does not contain a separate <u>sector</u> reader (CX DELTA Systems), the <u>sample bar code reader</u> window must be oriented with the hole in the bottom left corner.

NOTE

This procedure should be done monthly, or as needed.



Figure 9-53. Sample Bar Code Reader Window

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9.4.6 Replace Alkaline Buffer Peri-Pump Tubing (CX7 Users Only)

The alkaline buffer peri-pump tubing needs to be replaced on a monthly basis. All other pump tubing needs to be replaced after every two months of operation, or 5000 assays (Paragraph 9.5.3).

- 1. Prepare new peri-pump tubing as follows:
 - (a) Obtain one gray and one red peri-pump tubing:
 - Moisten a cotton-tipped applicator stick with 70% isopropanol and push it completely through the bore of the new pump tubing (Figure 9-54).
 - ii. If the cotton appears dirty, repeat the procedure with a new applicator swab. Make sure the second swab goes through the tubing in the same direction as the first swab.

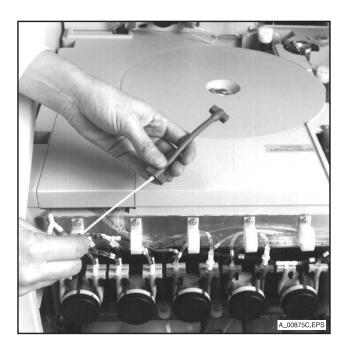


Figure 9-54. Cleaning Peri-Pump Tubing

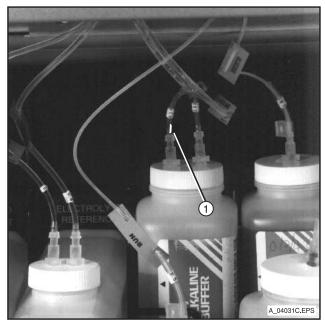
- iii. When installing tubing onto the peri-pump, orient it so that the fluid flows in the same direction as the cotton-tipped applicator was pushed.
- 2. Open the CX3 reagent compartment door.
- 3. Disconnect line #81 from the Alkaline Buffer bottle (Figure 9-55).

NOTE

Do not remove the drain tube (line #82) from the bottle. This line returns the alkaline buffer reagent to the bottle, so removing it could cause a spill.

4. Prime as follows:

- (a) From the MASTER Screen, press **F4 SPECIAL FUNCTION**.
- (b) Cursor and **SELECT** 1. Prime or type **1** and **ENTER**.
- (c) Cursor and **SELECT** Alkaline Buffer.
- (d) Press F1 START PRIME.
- (e) The operator is prompted to enter the number of prime cycles. Type 15 and press ENTER. The display indicates the number of primes remaining.
- (f) This will empty the lines of Alkaline Buffer.
- (g) Press MASTER SCREEN.



1 - Line 81

Figure 9-55. Alkaline Buffer

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- 5. When the system is finished priming, prevent the system from autopriming as follows:
 - (a) Press **F4 SPECIAL FUNC-TIONS**.
 - (b) Cursor and **SELECT** 6. Maintenance or type **6** and **ENTER**.
 - (c) Cursor and **SELECT** 9. CX3 Prevent Autoprime or type 9 and **ENTER**.
- CX7 DELTA Systems need the reagent compartment door open to access the peri-pump tubing. CX7 Systems need to have the reagent compartment door closed in order to lower the peri-pump cover and access the peri-pump tubing (Figure 9-56)
- 7. Remove one side of pump tubings from the support post by lifting and sliding it out of post. (Leave input and output lines attached.)
- 8. Remove other side of tubings from other support post in the same manner (Figure 9-57.)
- 9. Disconnect lines #31 and #82 from the gray tube. Discard the old gray tube.
- Attach line #31 to the end of the new gray tube through which the applicator was pushed. Attach line #82 to the other end.

CAUTION

To prevent damage to pump tubing, avoid rubbing pump tubing against corners of support posts.

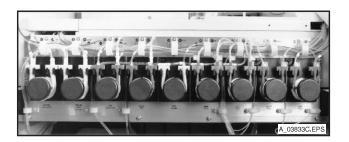
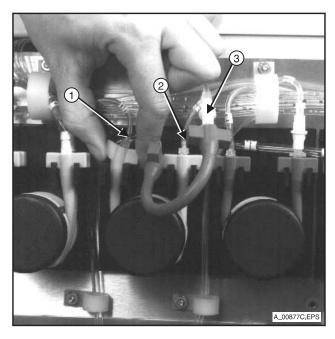


Figure 9-56. Peri-Pump Compartment



- 1 Line #31
- 2 Line #82
- 3 In-Line Filter

Figure 9-57. Alkaline Buffer Peri-Pump (Grey tubing)

- 11. Place the end attached to line #31 on the left tubing support post and stretch the tubing around the pump. Place the end attached to line #82 to the right tubing support post.
- 12. Disconnect lines #81 and #32 from the red tube. Leave in-line filter (Figure 9-58) connected to line #32. Discard old red tubing.
- 13. Attach line #81 to the end of the new red tube through which the applicator was pushed. Attach line #32 (with the in-line filter) to the other end.
- 14. Place the end attached to line #81 on the left tubing support post and stretch the tubing around the pump. Place the end attached to line #32 to the right tubing support post.
- Close peri-pump cover on CX7 systems which have this style cover.
 Open CX3 reagent compartment door.
- 16. Reconnect reagent line #81 into the Alkaline Buffer bottle.
- 17. Press **PREV SCREEN** and then press **MASTER SCREEN**.

NOTE

At this point it would be most efficient to continue directly to the procedure in Paragraph 9.4.7. to replace the Alkaline Buffer Reagent. If this is not desired continue as follows:

18. Prime as follows:

- (a) Press F4 SPECIAL FUNCTION.
- (b) Cursor and **SELECT** 1. Prime or type **1** and **ENTER**.
- (c) Cursor and **SELECT** Alkaline Buffer.
- (d) Press F1 START PRIME.
- (e) The operator is prompted to enter the number of prime cycles. Type 15 and press ENTER. The display indicates the number of primes remaining.

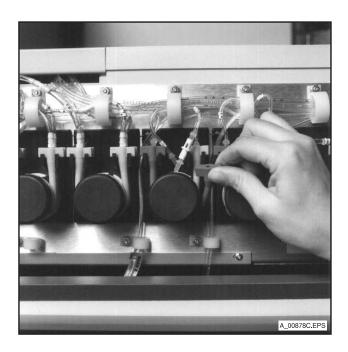


Figure 9-58. Alkaline Buffer Peri-Pump (red tubing)

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- (f) Inspect for leaks. (If any leaks are noticed, discontinue priming and correct the problem.)
- (g) Ensure that the alkaline buffer damper assembly returns to approximately half full (Paragraph 9.1.8).
- (h) Press **MASTER SCREEN** to conclude this procedure.
- (i) Close compartment door.

9.4.7 Replace Alkaline Buffer Reagent (CX7 Users Only)

To ensure optimum performance, the alkaline buffer reagent should be replaced once a month. This may be quickly and easily accomplished if the fresh reagent is placed on the system at step 16 of 9.4.6 (Alkaline Buffer Peri-pump Tubing Replacement).

- 1. Open the CX3 reagent compartment door.
- 2. Disconnect line #81 from the Alkaline Buffer bottle.

NOTE

Do not remove the drain tube (line #82) from the bottle. This line returns the alkaline buffer reagent to the bottle, so removing it could cause a spill.

- 3. Prime as follows:
 - (a) From the MASTER Screen, press F4 SPECIAL FUNCTION.
 - (b) Cursor and SELECT 1. Prime or type 1 and ENTER.
 - (c) Cursor and **SELECT** Alkaline Buffer.
 - (d) Press F1 START PRIME.
 - (e) Operator is prompted to enter the number of prime cycles. Type 15 and press ENTER. The display indicates the number of primes remaining.
 - (f) This will empty the lines of Alkaline Buffer.

- 4. Remove and discard the old reagent.
- Place a fresh bottle of Alkaline Buffer on the system. Reconnect line #81 and the Alkaline Buffer bottle. Close the reagent compartment door.
- 6. Perform a reagent load as follows:
 - (a) From the MASTER Screen, press **F2 REAGENT LOAD**.
 - (b) Press F3 CX3 LOAD.
 - (c) Cursor and **SELECT** Alkaline Buffer.
 - (d) Press F4 CONTINUE.
 - (e) Press F1 PRIME.

9.4.8 Clean BUN Electrode, Chemistry Reaction Cup Lines and Stirrer (CX7 Users Only)

The BUN chemistry reaction cup and stirrer should be cleaned every month or if a successful calibration, using the SYNCHRON CX Calibrators cannot be achieved.

Clean the BUN chemistry reaction cup and stirrer as follows:

- Open CX3 reagent compartment door.
- Remove reagent straw from the BUN concentrate reagent and place the straw in a beaker of warm DI water.
- 3. Perform a reagent load for BUN (refer to Section 6, Paragraph 6.2.3).
- 4. Prime the BUN module 10 times.
- Remove reagent straw from the water and put the straw into the BUN reagent bottle.
- Use the Adjust Volume function in Reagent Load (Paragraph 6.2.3) to match the current reagent level in the BUN bottle.
- Remove the front shield over the BUN, glucose and calcium or total protein chemistry reaction cups as follows:
 - (a) Unscrew and remove the three retaining nuts and one thumb screw. (Refer to Figure 9-31)
 - (b) Gently lift shield off.

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- 8. Prepare chemistry reaction cup for maintenance as follows:
 - (a) From the MASTER Screen, press **F4 SPECIAL FUNC-TIONS**.
 - (b) Cursor and **SELECT** 6. Maintenance Procedures or type **6** and **ENTER**.
 - (c) Cursor and **SELECT** 6. CX3 Chemistry Maintenance or type **6** and **ENTER**.
 - (d) Cursor and SELECT BUN3.
 - (e) Press F1 CONTINUE. This will drain the cup of reagent so that maintenance may be performed.
- 9. Disconnect red and black BUN pin leads from connector panel (Figure 9-59).
- Unscrew BUN electrode retainer nut and withdraw electrode-retainer assembly from chemistry reaction cup (Figure 9-60).

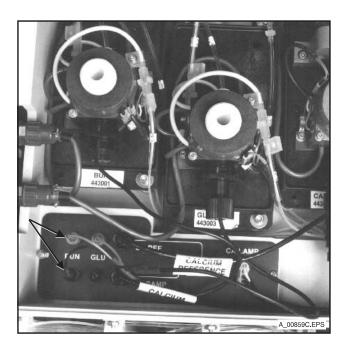
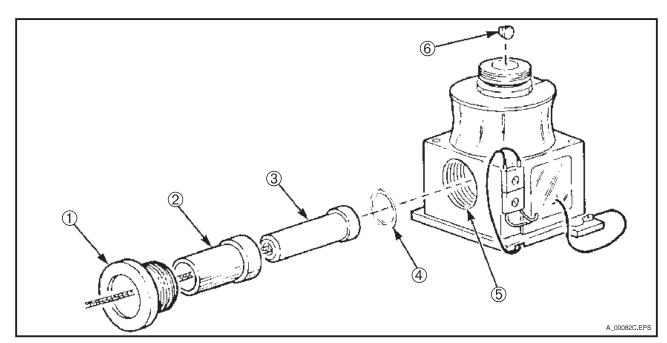


Figure 9-59. BUN Pin Leads



- 1 Retainer Nut
- 2 Retainer
- 3 Electrode
- 4 Quad-Ring
- 5 Mounting Port
- 6 Stirrer

Figure 9-60. BUN Electrode

 Separate electrode, retainer and retainer nut and set aside for later cleaning.

CAUTION

Always remove electrode (step 10) before removing stirrer (step 12). This prevents possible damage to the delicate electrode tip.

- 12. Extract white stirrer using Stirrer Removal Tool (P/N 671642) (Figure 9-61).
- 13. Clean white stirrer using lintless tissue dampened with 70% isopropanol.

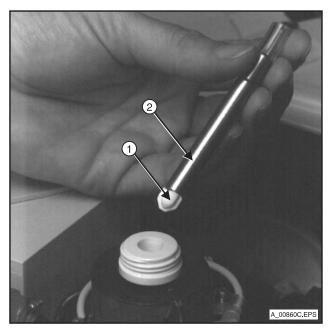
CAUTION

Stirrers must never be interchanged from one chemistry reaction cup to another, as contamination may occur.

- 14. Carefully wipe inside of chemistry reaction cup with cotton-tipped applicators saturated with 70% isopropanol and rolled between finger tips. Rolling the applicator tip compacts the cotton and reduces the possibility of leaving loose fibers in the cup.
- Using lintless tissue saturated with 70% isopropanol, clean electrode mounting port.
- 16. Using dry, lintless tissue, wipe electrode mounting port.
- 17. Reinstall stirrer in chemistry reaction cup as follows:
 - (a) Place stirrer (flat side up) on Stirrer Removal Tool.
 - (b) Lower stirrer to bottom of cup.
 - (c) Dislodge stirrer by twirling and rapidly lifting removal tool. Stirrer will remain in cup.
- 18. Remove black quad-ring from front face of electrode (Figure 9-62).

CAUTION

Avoid scratching gold coating on face of electrode as excessive scratching may adversely effect performance.



- 1 Stirrer
- 2 Stirrer Removal Tool

Figure 9-61. Extract Stirrer



Figure 9-62. BUN Electrode

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- 19. Rinse quad-ring in deionized water and dry using lintless tissue.
- 20. Use lintless tissue moistened with 70% isopropanol to clean electrode face until gold surface is bright. Rub parallel to the gap with tissue. Rinse with deionized water. Dry using lintless tissue.
- 21. Apply **thin** coating of Silicone Compound (P/N 879049) over tip of electrode. Carefully wipe electrode end parallel to the gap with lintless tissue to remove all evidence of compound. Rub to a bright finish.
- 22. Reinstall quad-ring on face of electrode.
- 23. Reinstall retainer on BUN electrode (Refer to Figure 9-60).
- 24. Rotate electrode until electrode key enters retainer keyway.
- 25. Reinstall retainer nut on electrode-retainer assembly.
- 26. Align keyway on body of retainer containing electrode with key in electrode port and install electrode assembly. Finger-tighten retainer nut.
- 27. Reconnect red and black BUN pin leads into connector panel (Refer to Figure 9-59).
- 28. Press PREV SCREEN.
- 29. Prime as follows:
 - (a) From the MASTER Screen, press **F4 SPECIAL FUNCTION**.
 - (b) Cursor and SELECT 1. Prime or type 1 and ENTER.
 - (c) Cursor and **SELECT** BUN3.
 - (d) Press F1 START PRIME.
 - (e) Operator is prompted to enter the number of prime cycles. Type 15 and press ENTER. The display indicates the number of primes remaining.

- 30. While module is priming, observe lines and chemistry reaction cup to determine if there are any leaks. Stop the priming if any leaks are noticed and correct the problem.
- 31. Observe stirrer to verify that it is rotating properly.

NOTE

If additional chemistry reaction cup maintenance procedures are to be performed, proceed to step 1 of the appropriate procedure. If this is the only chemistry reaction cup maintenance procedure being performed, proceed to step 32 of this procedure.

- 32. Carefully place shield over chemistry reaction cups. Take care that wires and tubes are not pinched under edges of cover.
- 33. Replace and secure the three retaining nuts and one thumb screw on the shield.
- 34. Close compartment door.

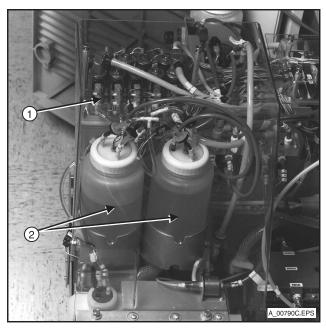
This completes the cleaning of the BUN electrode, chemistry reaction cup and stirrer. Allow 15 minutes for temperature stability before calibration and operation of this module.

9.5 TWO-MONTH MAINTENANCE PROCEDURES

CX4:

9.5.1 Check All Diluted Wash Bottles, Probe Rinse Bottle, and Float Sensors for Contamination

- 1. Turn off the hydropneumatic system as follows:
 - (a) From the MASTER Screen, press F4 SPECIAL FUNCTION.
 - (b) Cursor and SELECT 6. Maintenance Procedures or type 6 and ENTER.
 - (c) Cursor and **SELECT** 4. CX4 Hydropneumatic System Shutdown or type **4** and **ENTER**.
- Open the lower middle (left) compartment door.
- 3. Remove the plastic cover over the hydropneumatic system as follows: (Figure 9-63).
 - (a) Remove the two thumbscrews at the top of the cover. Carefully set aside for reinstallation.
 - (b) Remove the two thumbscrews on the lower right side of the cover. Carefully set aside for reinstallation.
 - (c) Remove plastic cover and set aside.
- 4. Remove the probe rinse bottle, and diluted wash bottles and inspect the contents, and inspect the float sensors for contamination. If contamination is noted, refer to Six-Month Maintenance procedure, Paragraph 9.7.2.
- Replace the probe rinse and wash bottles and press PREV SCREEN to complete procedure.
- 6. Replace plastic cover over the hydropneumatic system.
- 7. Close compartment door.



- 1 Cover
- 2 Diluted Wash Bottles

Figure 9-63. Removal of Hydropneumatic Cover

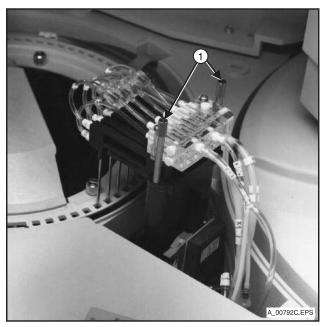
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8. CX7 users:

- (a) Open CX3 reagent compartment door.
- (b) Inspect CX3 wash solution container for contamination.
- (c) If contamination is noted, refer to As Needed Maintenance, System Decontamination, Paragraph 9.8.3. If no contamination is noted, close compartment door.

9.5.2 Replace the Silicone Wipers on Cuvette Washer Probes and Check for Proper Operation of Cuvette Washer Probes

- 1. Remove wash station cover. (Refer to Paragraph 9.1.3.)
- 2. Loosen the two thumbscrews on the left and right of the cuvette washer (Figure 9-64).



1 - Thumbscrews

Figure 9-64. Cuvette Wash Station

- 3. Lift off the upper section of the cuvette wash assembly (Figure 9-65). Pull off the two silicone wipers located on probes 5 and 6.
- Install new wipers (P/N 759927) by sliding them onto the bottom of the probes until the undersurface of the wipers is flush with the end of the probes.

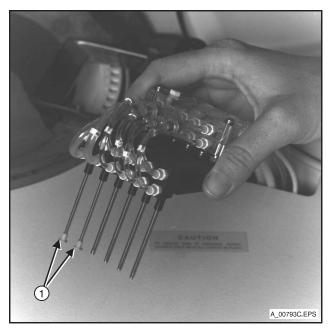
The following steps outline the procedure used to check the cuvette washer probes. If the cuvette wash station probes are obstructed by debris (such as glass from broken cuvettes), the SYNCHRON CX may provide inaccurate results. If any of these steps fail, consult the Clinical Support Center to identify and resolve any suspected problems.

- 5. Hold wash station probes 1 through 4 over a beaker.
- 6. Prime the wash lines.
 - (a) From the MASTER Screen, press the F4 SPECIAL FUNC-TION key.
 - (b) Move the cursor to 1. Prime and press the **SELECT** key.
 - (c) Move the cursor to CUVETTE WASH LINES and press the **SELECT** key.
 - (d) Press F1 START PRIME.
- 7. Observe the wash probe spray pattern during the prime. There should be three distinct and straight streams in a triangular pattern.

NOTE

If a pattern of distinct streams is not observed during prime, check for proper water pressure in the hydropneumatic system. If the water pressure is adequate, check the probe tips for broken glass (see Step 8).

8. Turn the wash station so that the tips of the probes can be examined. Inspect for glass from cuvettes or other debris which could block the probes. If the probes appear to be blocked, call the Clinical Support Center to resolve the problem.



1 - Silicone Wipers

Figure 9-65. Cuvette Wash Assembly

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- Place each of the first four wash probes into four 13 x 100 mm test tubes (one probe per test tube). Be careful to keep the probes above the surface of the liquid.
- 10. Prime the wash lines:
 - (a) From the MASTER Screen, press the **F4 SPECIAL FUNC-TION** key.
 - (b) Move the cursor to 1. Prime and press the **SELECT** key.
 - (c) Move the cursor to CUVETTE WASH LINES and press the **SELECT** key.
 - i. Observe the amount of liquid that is delivered to the test tubes.
 - ii. The volume in tube 1 should be approximately equal to the volume in tube 2.
 - iii. The contents of tubes 1 and 2 should appear "soapy".
 - iv. The volume in tube 3 should be approximately equal to the volume in tube 4.
 - v. The contents of tubes 3 and 4 should appear clear.
 - vi. The volumes in tubes 1 and 2 should be approximately 20% greater than the volumes in tubes 3 and 4.

NOTE

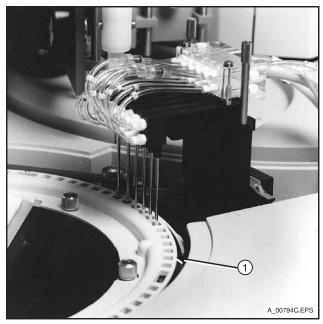
Unlike running a test, precise volumes are not required for washing and rinsing.

11. Hold probes 1 through 4 at the bottom of four 2.0 mL sample cups (1 probe per cup).

NOTE

Do not push the probes against the bottom of the sample cups. This will restrict the vacuum.

- 12. Prime the wash lines.
 - (a) From the MASTER Screen, press the **F4 SPECIAL FUNC-TION** key.
 - (b) Move the cursor to 1. Prime and press the **SELECT** key.
 - (c) Move the cursor to CUVETTE WASH LINES and press the **SELECT** key.
 - (d) Press F1 START PRIME.
- 13. Observe the cups at the end of the prime cycle. This step is performed to ensure that the contents of the cuvettes are being completely evacuated at the end of each cleaning step. Therefore, there should be no liquid remaining at the end of each prime cycle.
- 14. Replace the upper section of the cuvette wash assembly and tighten the screws finger-tight (Figure 9-64).
- 15. Orient the wipers square to the cuvette opening in the cuvette retaining ring (Figure 9-66).
- 16. Tighten the two thumbscrews on the left and right of the cuvette washer (Figure 9-64).
- 17. Replace the wash station cover.



1 - Cuvette Retaining Ring

Figure 9-66. Cuvette Wash Station

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CX3: NOTE

9.5.3 Replace All CX3 Peri-Pump Tubing (CX7 Users Only)

The alkaline buffer peri-pump tubing needs to be replaced on a monthly basis (Paragraph 9.4.6). All other pump tubing needs to be replaced after every two months of operation (or 5000 assays).

NOTE

It is recommended that you replace one peri-pump tubing at a time.

- 1. Prepare new peri-pump tubing as follows:
 - (a) For Gray and Red Pump Tubing:
 - Moisten a cotton-tipped applicator stick with 70% isopropanol and push it completely through the bore of the new pump tubing.
 - ii. If the cotton appears dirty, repeat the procedure with a new applicator swab. Make sure the second swab goes through the tubing in the same direction as the first swab.
 - iii. Set aside for later installation.
 - (b) For Green Tubing:
 - i. Attach a green tube fitting (P/N 439561) to the pump tubing.
 - ii. Fill a 10-mL Luer-lock syringe with 70% isopropanol and attach to the green fitting.
 - iii. Flush the peri-pump tubing with the alcohol, followed by a syringe full of air.
 - iv. Install tubing onto the peri-pump so that the fluid flows in the same direction as the tubing was flushed.
 - v. Set aside for later installation.
- 2. Disconnect reagent lines as follows:

84-Wash Solution

4-Electrolyte Buffer

6-CO₂ Acid Reagent

2 & 83-Electrolyte Reference

85-BUN

89-Calcium or total protein

90-Creatinine

87-Glucose

81-CO₂ Alkaline Buffer

Do not remove the CO_2 Alkaline Buffer drain tube (line #82) from the bottle. This line returns the alkaline buffer reagent to the bottle, so removing it could cause a spill.

3. Prime as follows:

- (a) From the MASTER Screen, press **F4 SPECIAL FUNCTION**.
- (b) Cursor and SELECT 1. Prime or type 1 and ENTER.
- (c) Cursor and **SELECT** all CX3 modules.
- (d) Press F1 START PRIME.
- (e) Operator is prompted to enter the number of prime cycles. Type 10 and press ENTER. The display indicates the number of primes remaining.
- 4. When the system is finished priming, prevent the system from autopriming as follows:
 - (a) Press F4 SPECIAL FUNCTIONS.
 - (b) Cursor and **SELECT** 6. Maintenance or type **6** and **ENTER**.
 - (c) Cursor and **SELECT** 9. CX3 Prevent Autoprime or type **9** and **ENTER**.
- 5. CX7 DELTA Systems need the reagent compartment door open to access the peri-pump tubing. CX7 Systems need to have the reagent compartment door closed in order to lower the peri-pump cover and access the peri-pump tubing (Figure 9-56).
- 6. Remove input and output line connections to pump tubing.
- 7. Remove one side of pump tubing from support post by lifting and sliding it out of post.
- Remove tubing from other support post in same manner.

CAUTION

To prevent damage to pump tubing, avoid rubbing pump tubing against corners of support posts.

NOTE

In-line filters can be replaced during this procedure (Refer to paragraph 9.5.4).

- Install the new tubing (prepared in step 1) as follows:
 - (a) Place the end of new pump tubing through which the applicator (or alcohol) was pushed onto the left support post.
 - (b) Route tubing down and around pump reel.
 - (c) Stretch the tubing down and around the pump and carefully slip tubing into place on the right support post.
- 10. Reconnect input and output lines to fittings on new pump tubing.
- 11. Repeat steps 7 through 10 for each tube that is being replaced.
- 12. Reconnect reagent lines to appropriate bottle (Refer to step 2 for proper placement).
- Press PREV SCREEN and then press MAS-TER SCREEN.
- 14. Prime as follows:
 - (a) From the MASTER Screen, press **F4 SPECIAL FUNCTION**.
 - (b) Cursor and SELECT 1. Prime or type 1 and ENTER.
 - (c) Cursor and SELECT all CX3 Chemistries.
 - (d) Press F1 START PRIME.
 - (e) Operator is prompted to enter the number of prime cycles. Type 25 and press ENTER. The display indicates the number of primes remaining.
- 15. While the system is priming, observe the peripump tubes and reagent and waste lines for leaks. Stop the priming should any leaks be noticed and correct the problem.
- 16. Close peri-pump cover.

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9.5.4 Replace Peri-Pump Assembly In-line Filters (CX7 Users Only)

- Prevent the system from autopriming as follows:
 - (a) Press F4 SPECIAL FUNCTIONS.
 - (b) Cursor and **SELECT** 6. Maintenance or type **6** and **ENTER**.
 - (c) Cursor and **SELECT** 9. CX3 Prevent Autoprime or type **9** and **ENTER**.
- On CX7 DELTA systems, open the reagent compartment door. On CX7 Systems lower peri-pump cover. In-line filters are located at the alkaline buffer and electrolyte reference peripump assemblies.
- 3. Clamp and remove reagent output (right) line from the top of the appropriate in-line filter.
- 4. Remove the in-line filter from the connector on the peri-pump tubing by gently twisting and pulling upward on the filter.
- 5. Replace the in-line filter (P/N 669212).

NOTE

When installing in-line filters, be sure the arrow on the filter is pointing upwards in the direction of reagent flow.

- After installation of the filter is complete, reattach the reagent output (right) line to the top of the filter.
- Repeat Steps 3 through 5 for the other in-line filters.
- 8. Press PREV SCREEN or MASTER SCREEN.
- Close reagent compartment door or peri-pump cover.

9.5.5 Clean Chloride Electrode (CX7 Users Only)

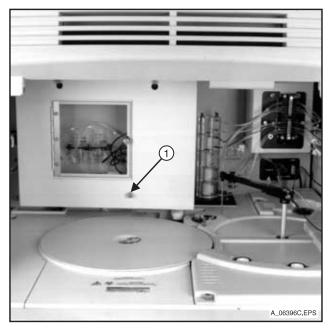
With daily use, the sensing element of the chloride electrode may become etched or poisoned, or may lose its sensitivity in response to chloride ions. This procedure is designed to restore chloride electrode performance and MUST be performed following the Enzymatic Flow Cell cleaning procedure (Paragraph 9.8.12).

NOTE

A spare chloride electrode has been provided in the CX3 Maintenance Kit. To decrease instrument down time: 1) Prepare the spare electrode for installation (step 10), 2) remove the chloride electrode from the instrument (steps 1-8), and then 3) install the previously prepared spare electrode (steps 11-19).

To remove the chloride electrode:

- 1. Remove the flow cell cover as follows:
 - (a) Loosen the captive screw at the bottom of the flow cell cover (Figure 9-67).
 - (b) Grasp the flow cell cover.
 - (c) Carefully lift up and over the two fixed guide screws.
 - (d) Set the cover aside for later reinstallation.



1 - Captive Screw

Figure 9-67. Removing Flow Cell Cover

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- Prevent the system from autopriming as follows:
 - (a) Press **F4 SPECIAL FUNC-TIONS**.
 - (b) Cursor and **SELECT** 6. Maintenance or type **6** and **ENTER**.
 - (c) Cursor and **SELECT** 9. CX3 Prevent Autoprime or type **9** and **ENTER**.
- 3. Disconnect the chloride electrode cable (Figure 9-68).
- 4. Using a hemostat or tube clamp, securely clamp the TOP FRONT electrolyte drain tubing (line #71) approximately one inch (25 mm) from the top of the flow cell (Figure 9-69). This will prevent the back flow of reagent into the flow cell.
- 5. Using another tube clamp or hemostat, clamp off the FRONT TOP CO₂ Acid tubing (line #57) on the front of the flow cell as close to the connector as possible (Figure 9-69). This will prevent acid flow into the flow cell.

NOTE

Do NOT disconnect any of the reagent lines attached to the flow cell or remove any tubing from the flow cell or solenoid valve.

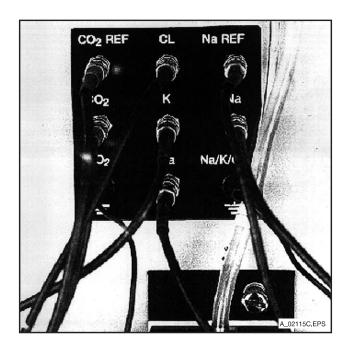
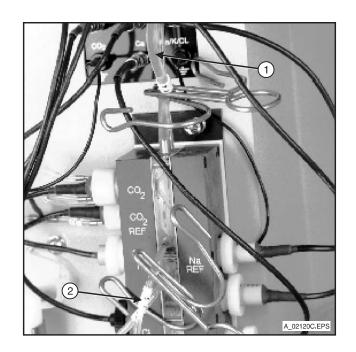


Figure 9-68. Chloride Electrode Cable



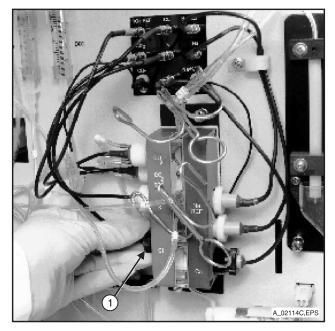
1 - Line #71 2 - Line #57

Figure 9-69. Flow Cell Lines #71 and #57 Clamped

- Locate the chloride electrode (Figure 9-70). Remove electrode by turning the electrode retainer nut counterclockwise.
- 7. Remove the retainer nut from the electrode.
- 8. Remove the quad-ring from the electrode tip (Figure 9-71). If the quad-ring is not on the electrode tip, inspect the electrode port. If the quad-ring is in the port, remove it carefully.

CAUTION

Excessive pressure (in step 9) could shorten the electrode tip length such that the seal used on the electrode tip will no longer fit properly.



1 - Retainer Nut

Figure 9-70. Chloride Electrode



1 - Quad-Ring

Figure 9-71. Chloride Electrode

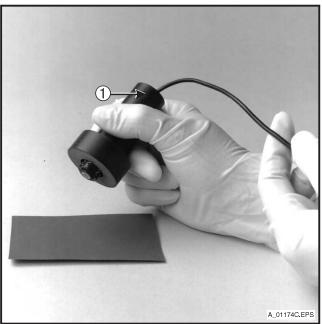
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9. To clean the electrode:

Clean the chloride electrode. A spare electrode that is rotated into maintenance intervals is ideal, as the spare can be installed on the system immediately to minimize maintenance down time. The dirty electrode can be cleaned as follows and prepared for the next maintenance interval. Note that the minimum recommended airdrying time for the electrode is two weeks.

(a) With the Cleaning tool:

- i. Insert the chloride electrode into the electrode cleaning tool (Figure 9-72). The spring inside the tool should be at least 1/4 inch down from the top of the tool for the appropriate tension. The spring can be adjusted down by turning it counter clockwise.
- ii. Place a drop of electrolyte reference solution on the abrasive strip (Beckman P/N 440496). Holding the cleaning tool perpendicular to the abrasive strip and using even pressure, draw the electrode cleaning across the abrasive strip in a figure-8 motion so that the surface of the electrode tip remains flat and attains a shiny surface (Figure 9-73). This may take 20 to 25 strokes of moderate pressure. The new surface of the electrode should be uniform. smooth and have no dark sections.



1 - Inner Spring Applies Tension for Electrode Cleaning.

Figure 9-72. Electrode Cleaning Tool

- iii. Remove the electrode from the cleaning tool. Remove any residue from the tip by lightly wiping the tip with a lint free tissue moistened with Electrolyte Reference Solution. Apply a thin coat of Silicone Compound (P/N 879049) to the surface of the electrode tip. Wipe the excess compound from the tip of the electrode with a lint free tissue so that only a nonvisible thin coat remains.
- iv. Holding the <u>electrode</u>, rub the electrode tip across the abrasive strip with three light strokes using a clean area of the abrasive strip for each stroke.
- v. Rinse the tip of the electrode with electrolyte reference reagent and pat the electrode surface dry with a lint free tissue. DO NOT apply any more silicone compound.
- vi. Let the electrode air dry for a minimum of two weeks before reinstallation (if it is rotated with a spare electrode). Reinstall the electrode at the next maintenance interval.
- vii. Proceed to Step 11.
- (b) Without the Cleaning tool:
 - i. Place a drop of electrolyte reference solution on the abrasive strip (P/N 440496). Rub the electrode tip on the abrasive strip, by drawing it across the strip in a figure-8 motion using even pressure so that the surface of the electrode tip remains flat and attains a shiny surface (Figure 9-73). This may take 6 to 10 strokes of moderate pressure.



Figure 9-73. Roughening Chloride Electrode Cleaning Tip

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- ii. Remove any residue from the tip by lightly wiping the tip with a lint free tissue moistened with Electrolyte Reference Solution.
- iii. Rub a thin coat of silicone compound (P/N 879049) into the porous surface of the electrode tip. Wipe off the excess compound with a lint free tissue until only a nonvisible thin coat remains.
- iv. Rub the electrode tip on the abrasive strip with 3 strokes of light pressure (about half the pressure used in Step i). Use a clean area of the abrasive paper for each stroke.
- Rinse with Electrolyte Reference to remove any residue and dry with lintless tissue. DO NOT reapply any silicone compound.
- vi. Let the electrode air dry for a minimum of two weeks before reinstallation (if it is rotated with a spare electrode). Reinstall the electrode at the next maintenance interval.
- vii. Proceed to Step 10.

To reinstall the chloride electrode:

- 10. Place a new quad-ring (P/N 669229) on the electrode.
- 11. Replace the retainer nut on the electrode.
- 12. Using EXTREME CAUTION, thoroughly dry the electrode port with lint free tissue.

CAUTION

DO NOT pack tissue into port as damage to the flow cell may occur, thus adversely affecting performance.

- Insert electrode into electrode port and turn electrode retainer nut clockwise until fingertight.
- 14. To test for proper seating of electrode, gently pull on electrode body. The electrode assembly should not move. If electrode moves, remove it and try to install it once again. Check for an extra or missing quad-ring if installation is difficult
- Reconnect electrode cable to the appropriate connector.
- 16. Remove hemostats or clamps from the tubing.

- Press PREV SCREEN to conclude this procedure. Allow system to reinitialize. Press MASTER SCREEN.
- 18. Prime as follows:
 - (a) From the MASTER Screen, press F4 SPECIAL FUNCTION.
 - (b) Cursor and SELECT 1. Prime or type 1 and ENTER.
 - (c) Cursor and SELECT Wash Solution, Ratio Pump, Electrolyte Ref. Flow Cell, Electrolyte Ref. Ratio Pump and Alkaline Buffer.
 - (d) Press F1 START PRIME.
 - (e) Operator is prompted to enter the number of prime cycles. Type 20 and press ENTER. The display indicates the number of primes remaining.
- 19. Reinstall the flow cell cover and secure the captive screw. Be careful not to pinch tubing

9.5.6 Clean or Replace CX3 Electronics Compartment and Power Supply Compartment Air Filters

NOTE

To minimize system down time, it is recommended that you have one clean electronics compartment air filter (P/N 443674) and two clean power supply compartment air filters (P/N 450830) on hand. This will allow you to install the clean filters and clean the dirty filters at your convenience.

- 1. Electronics Compartment Air Filter:
 - (a) Remove the CX3 electronics compartment cover as follows:

CX7 Systems:

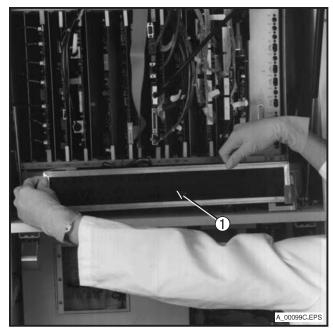
- i. Loosen the two captive screws.
- ii. Lift the top panel off the system.

CX7 DELTA Systems:

- Unlock latches under the electronics compartment cover.
- ii. Lift cover carefully up to resting position.
- (b) The air filter is located just below the circuit boards. Grasp the filter by the corners and lift up and out (Figure 9-74).
- (c) Rinse the filter thoroughly with deionized water. Vigorously shake residual water from the filter. Allow the filter to air dry completely.

CAUTION

When installing air filter, DO NOT snag filter on circuit board release levers as damage to the filter may result.



1 - Air Filter

Figure 9-74. CX3 Electronics Compartment Air Filters

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(d) Once filter is completely dry, reinstall into position with the diamond shaped aluminum mesh toward the rear of the instrument.

CAUTION

DO NOT place a damp filter back onto the system. Residual moisture may cause damage to the system.

- (e) Reinstall the CX3 electronics compartment cover as follows:
 - i. Replace top panel onto the system.
 - ii. Secure the two captive screws.
- 2. CX3 Power Supply Air Filters:
 - (a) Open the CX3 reagent compartment door.
 - (b) Grasp the air filters by the corners and pull straight up and out of holder (Refer to Figure 9-75).
 - (c) Rinse the filters thoroughly with deionized water. Vigorously shake residual water from the filters. Allow the filters to air dry completely.
 - (d) Once the filters have completely dried, reinstall into positions with the diamond shaped aluminum mesh facing the fans.

CAUTION

DO NOT place a damp filter back onto the system. Residual moisture may cause damage to the system.

(e) Close the reagent compartment door.



Figure 9-75. CX3 Power Supply Air Filters

9.6 THREE-MONTH MAINTENANCE PROCEDURES

9.6.1 Replace Sample Syringe Plunger Rod (50 μ L) and Tip

The sample syringe plunger rod assembly and the brown plunger guide should be replaced every three (3) months, after every 130,000 assays, or if signs of wear are noticed, whichever comes first.

Replace as follows:

- 1. Remove the syringe cover (Refer to paragraph 9.1.5).
- Fully extend the plunger rod to the bottom of the syringe barrel as follows:
 - (a) From the MASTER Screen, press F4 SPECIAL FUNCTION.
 - (b) Cursor and SELECT 6. Maintenance Procedures or type 6 and ENTER.
 - (c) Cursor and **SELECT** 3 CX4 Syringe Tip Replacement or type **3** and **ENTER**.
- 3. Unscrew the barrel of the sample syringe to release the syringe. Loosen the round coupling nut at the base of the plunger rod of the syringe and remove the syringe from the system.

NOTE

The plunger rod cannot be pulled through the brown plunger guide.

4. Separate the plunger rod from the barrel by unscrewing the brown plunger guide at the base of the barrel and pull the plunger rod out of the barrel (Figure 9-76).

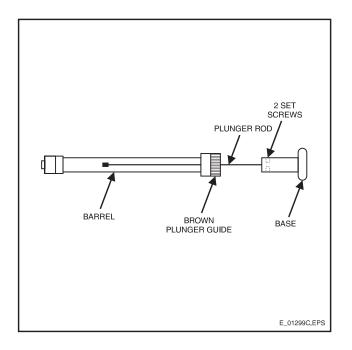


Figure 9-76. Sample Syringe with Plunger Rod and Attached Tips

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5. Using the provided hex wrench, loosen the two (2) set screws in the base of the plunger rod each one full turn and separate the plunger rod from the base (Figure 9-76).

NOTE

Do not remove the two (2) set screws from the base.

Remove the brown plunger guide from the plunger rod. Discard the plunger rod and the brown plunger guide.

- Moisten the replacement plunger rod with de-ionized water to limit the amount of air bubbles and insert the tipped end of the plunger rod into the syringe barrel. Gently push until the black plunger rod tip reaches the other end of the barrel
- Slide the replacement brown plunger guide over the exposed part of the plunger rod and gently screw the brown plunger guide onto the barrel finger-tight (Figure 9-77).
- 8. Insert the exposed part of the plunger rod through the base and gently push until the base touches the brown plunger guide (Figure 9-78).
- 9. Tighten the two (2) set screws in the base using the provided hex wrench.
- Reinstall the assembled syringe unit as follows:
 - (a) Insert the base of the plunger rod into the white plastic coupling.
 - (b) Re-tighten the round coupling nut finger-tight.
 - (c) Carefully pull the syringe barrel upward until the syringe Luerlock fitting is engaged.
 - (d) Turn the syringe barrel and lock in place.

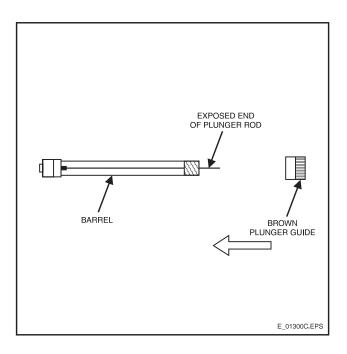


Figure 9-77. Replacement of Plunger Rod

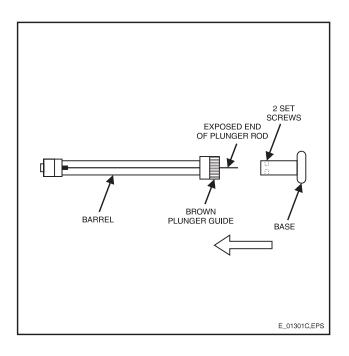


Figure 9-78. Attachment of Plunger Rod to Base

11. Press **PREV SCREEN** to drive the plunger rod to the top of the syringe unit.

NOTE

If a motion error on the syringe occurs, the plunger base may not be properly seated in the white plastic coupling. Repeat Step 10.

- 12. If bubbles are present in either syringe, prime as follows:
 - (a) From the MASTER Screen, press F4 SPECIAL FUNC-TIONS.
 - (b) Cursor and SELECT 1. Prime or type 1 and ENTER.
 - (c) Cursor and **SELECT** Internal Probe Wash.
 - (d) Press F1 START PRIME.
 - (e) Repeat Steps c and d ten (10) times.
- 13. If bubbles persist after priming:
 - (a) Remove the syringe assembly and fill half full with de-ionized water.
 - (b) Tap syringe to release bubbles.
 - (c) Reinstall the syringe unit as described in Step 10.
 - (d) Prime Internal Probe Wash as described in Step 12.
- 14. Press **MASTER SCREEN** to conclude this procedure.
- 15. Replace syringe cover.

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9.6.2 Replace Reagent Syringe Plunger Rod (500 μ L) and Tip

The reagent syringe plunger rod assembly should be replaced every three (3) months, after every 130,000 assays, or if signs of wear are noticed, whichever comes first.

Replace as follows:

- 1. Remove the syringe cover (Refer to paragraph 9.1.5).
- Fully extend the plunger rod to the bottom of the syringe barrel as follows:
 - (a) From the MASTER Screen, press F4 SPECIAL FUNCTION.
 - (b) Cursor and SELECT 6. Maintenance Procedures or type 6 and ENTER.
 - (c) Cursor and SELECT 3 CX4 Syringe Tip Replacement or type 3 and ENTER.
- 3. Unscrew the barrel of the reagent syringe to release the syringe. Loosen the round coupling nut at the base of the plunger rod of the syringe and remove the syringe from the system.
- Separate the plunger rod from the barrel by unscrewing the brown plunger guide at the base of the barrel and pull the plunger rod out of the barrel (Figure 9-79).

NOTE

The plunger rod cannot be pulled through the brown plunger guide.

- 5. Remove plastic protective cover from replacement rod tip.
- Moisten the replacement plunger rod tip with de-ionized water to limit the amount of air bubbles and insert the tipped end of the plunger rod into the syringe barrel (Figure 9-80).
- 7. Screw the brown plunger guide onto the barrel finger-tight.
- 8. Reinstall the assembled syringe unit as follows:
 - (a) Insert the base of the plunger into the white plastic coupling.

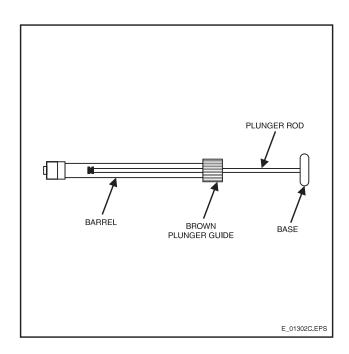


Figure 9-79. Reagent Syringe with Plunger Rod and Attached Tips

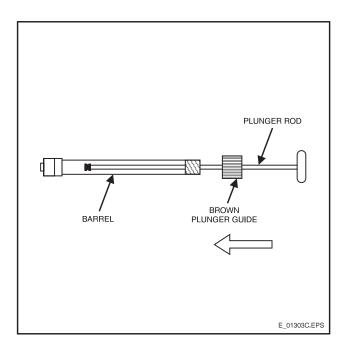


Figure 9-80. Replacement of Plunger Rod

- (b) Re-tighten the round coupling nut finger-tight.
- (c) Carefully pull the syringe barrel upward until the syringe Luerlock fitting is engaged.
- (d) Turn the syringe barrel and lock in place.
- 9. Press **PREV SCREE**N to drive the plunger to the top of the syringe unit.

NOTE

If a motion error on the syringe occurs, the plunger base may not be properly seated in the white plastic coupling. Repeat Step 7.

- 10. If bubbles are present in either syringe, prime as follows:
 - (a) From the MASTER Screen, press **F4 SPECIAL FUNC-TIONS**.
 - (b) Cursor and SELECT 1. Prime or type 1 and ENTER.
 - (c) Cursor and **SELECT** Internal Probe Wash.
 - (d) Press F1 START PRIME.
 - (e) Repeat Steps c and d ten (10) times.
- 11. If bubbles persist after priming:
 - (a) Remove the syringe assembly and fill half full with de-ionized water.
 - (b) Tap syringe to release bubbles.
 - (c) Reinstall the syringe unit as described in Step 7.
 - (d) Prime Internal Probe Wash as described in Step 9.
- 12. Press **MASTER SCREEN** to conclude this procedure.
- 13. Replace syringe cover.

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CX4:

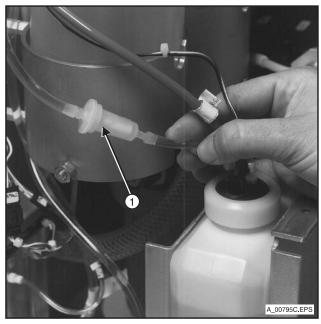
9.7.1 Replace the Wash Concentrate In-line Filter

- 1. Open the lower middle compartment door.
- 2. Turn off the hydropneumatic system as follows:
 - (a) From the MASTER Screen, press **F4 SPECIAL FUNCTION**.
 - (b) Cursor and SELECT 6. Maintenance Procedures or type 6 and ENTER.
 - (c) Cursor and **SELECT** 4. CX4 Hydropneumatic System Shutdown or type **4** and **ENTER**.
- 3. Remove the plastic cover over the hydropneumatic system. (Refer to Paragraph 9.5.1, Step 3.)
- Loosen cap slowly on wash concentrate bottle.

CAUTION

To avoid possible reagent splashing, allow all residual pressure to bleed out of the system (through the loosened wash cap) before proceeding to the next step.

- 5. Disconnect tubing from both sides of the filter (Figure 9-81).
- Install new filter (there are two styles of filter, both P/N 946766). Be sure the arrow (if arrow appears on filter) on the filter is pointing away from the wash bottle (Figure 9-82). Reconnect tubing.
- 7. Tighten cap on wash concentrate bottle.
- 8. Replace plastic cover over the hydropneumatic system.
- Press PREV SCREEN to conclude this procedure.
- 10. Close compartment door.



1 - In-Line Filter

Figure 9-81. Wash Concentrate In-Line Filter

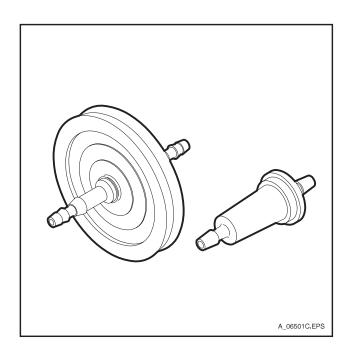
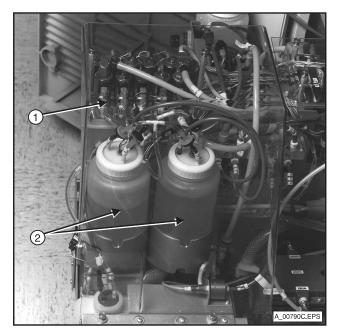


Figure 9-82. In-Line Filter (2 Styles)

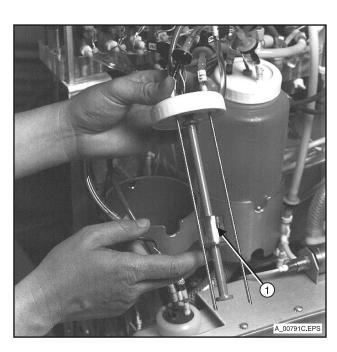
9.7.2 Clean All Diluted Wash Bottles, Probe Rinse Bottle and Float Sensors

- Turn off the hydropneumatic system as follows: (If the system has been in STANDBY for one hour, it may already be off; if so, continue to Step 2.)
 - (a) From the MASTER Screen, press **F4 SPECIAL FUNCTION**.
 - (b) Cursor and **SELECT** 6. Maintenance Procedures or type 6 and **ENTER**.
 - (c) Cursor and **SELECT** 4. CX4 Hydropneumatic System Shutdown or type **4** and **ENTER**.
- 2. Open the lower middle compartment door.
- 3. Remove the plastic cover over the hydropneumatic system. (Figure 9-83).
- 4. Remove the diluted wash bottles and probe rinse bottle located on the inside of the hydropneumatic door. Clean the inside of bottle caps with 10% bleach solution (Figure 9-83). Empty contents and fill with a 10% bleach solution.
- 5. Replace the bottles on the system and allow to sit for 15 minutes.
- Remove bottles, empty contents, and rinse thoroughly with deionized water.
 Fill with clean deionized water and place bottles back on system. Agitate to rinse bleach off of float sensors.
- 7. Repeat Step 6.
- 8. Dilute new probe rinse solution in the clean bottle and place on the system. Thoroughly rinse wash bottles with distilled or deionized water. Be sure that the float sensors move freely (Figure 9-84).
- 9. Place cleaned, empty wash bottles back on the system. Return caps to bottles and tighten.



- 1 Cover
- 2 Diluted Wash Bottles

Figure 9-83. Removal of Hydropneumatic Cover



1 - Float Sensor

Figure 9-84. Inspect Float Sensor

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10. Press PREV SCREEN.

- 11. Fill wash bottles as follows:
 - (a) From the MASTER Screen, press **F4 SPECIAL FUNCTION**
 - (b) Cursor and **SELECT** 1. Prime or type **1** and **ENTER**.
 - (c) Cursor and SELECT Fill Wash Bottles.
 - (d) Press F1 START PRIME.
 - (e) Check for leaks around the Oring on the bottle cap.
- 12. Replace the plastic cover.
- 13. Close the compartment door.

CX3:

9.7.3 Replace Potassium Electrode Tip

Preparing the Electrode Tip:

- 1. Prepare soaking solution as follows:
 - (a) Combine one (1) part concentrated Electrolyte Buffer with four (4) parts CX3 wash solution. Mix well.
 - (b) Combine one (1) part Electrolyte Reference Reagent with 19 parts of the diluted Electrolyte Buffer (from Step 1a). Mix well.
 - (c) Pour the soaking solution into a small beaker or glass container to a depth not to exceed two inches (50 mm).
- Unpack a new potassium electrode tip (P/N 669117). Very carefully remove the knurled protective cap from membrane end of tip assembly. Verify that the black protective cover on the internal threaded connector end of tip assembly is in place (Figure 9-85).



1 - Protective Cap

Figure 9-85. Potassium Electrode Tip

3. Lower assembly with the membrane facing down into the soaking solution until it floats (Figure 9-86). For maximum initial operational stability, the ideal soaking time is 24 hours. The minimum required time is one hour.

NOTE

If maximum soaking time is not allowed, the new electrode may require a few hours of operation to achieve complete electrical stability. During this period of time, more frequent calibration than normal may be required in response to system error messages. Assay results will not be compromised during this time.

- After soaking is completed, remove the tip from the soaking solution and dry sides using a lintless tissue. DO NOT touch electrode tip.
- Remove the black protective cover from the potassium tip. Check for the presence of moisture. Remove any moisture using lintless tissue.

Potassium Electrode Tip Removal:

- 6. Prevent the system from autopriming as follows:
 - (a) Press **F4 SPECIAL FUNC-TIONS**.
 - (b) Cursor and **SELECT** 6. Maintenance or type **6** and **ENTER**.
 - (c) Cursor and **SELECT** 9. CX3 Prevent Autoprime or type **9** and **ENTER**.
- 7. Remove the flow cell cover as follows:
 - (a) Loosen the captive screw at the bottom of the flow cell cover (Figure 9-87).
 - (b) Grasp the flow cell cover.
 - (c) Carefully lift up and over the two fixed guide screws.



Figure 9-86. Soaking the Electrode Tip



1 - Retaining Screw

Figure 9-87. Removing Flow Cell Cover

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- (d) Set the cover aside for later reinstallation.
- 8. Disconnect the potassium electrode cable. (Figure 9-88).

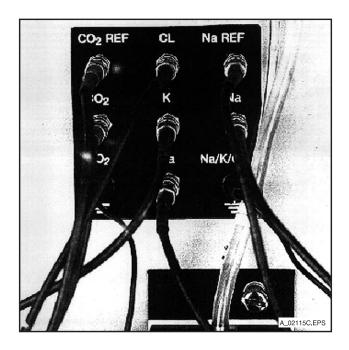
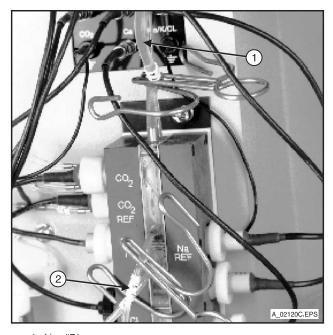


Figure 9-88. Potassium Electrode Cable

- Using a tube clamp or hemostat, securely clamp the TOP FRONT electrolyte drain tubing (line #71) approximately one inch (25 mm) from the top of the flow cell. This will prevent the back flow of reagent into the flow cell (Figure 9-89).
- 10. Using another tube clamp or hemostat, clamp off the FRONT TOP CO₂ Acid tubing (line #57) on the front of the flow cell as close to the connector as possible. (Figure 9-89). This will prevent acid flow into the flow cell.



1 - Line #71 2 - Line #57

Figure 9-89. Clamp Tubing

- 11. Locate the potassium electrode. Remove electrode by turning the electrode retainer nut counterclockwise (Figure 9-90).
- 12. Remove the quad-ring from the electrode tip. Inspect the electrode port if the quad-ring is not on the electrode tip. If the quad-ring is in the port, carefully remove it.
- Unscrew the OLD tip from the electrode assembly and remove the Oring. Discard the old O-ring and electrode tip.

Potassium Electrode Tip Replacement:

- 14. Install a new O-ring on the PRE-SOAKED potassium electrode tip and screw onto the electrode body (Figure 9-91).
- 15. Place the new quad-ring (P/N 669229) on the potassium electrode assembly (Figure 9-91).

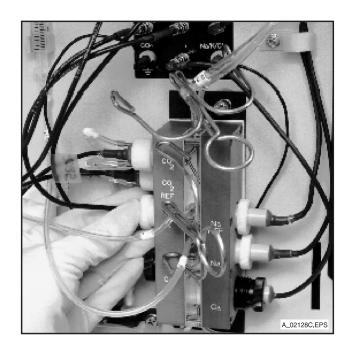
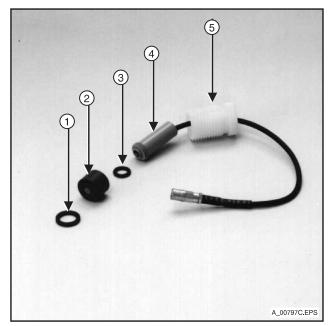


Figure 9-90. Remove Potassium Electrode

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- 16. Thoroughly dry the electrode port with lintless tissue. DO NOT pack tissue into port as damage to the flow cell may occur, thus adversely affecting performance.
- 17. Place the retainer nut on the potassium electrode and insert electrode into electrode port. Turn electrode retainer nut until finger-tight.
- 18. To test for proper seating of electrode, gently pull on electrode body. The electrode assembly should not move. If electrode moves, remove it and install it once again. If installation is difficult, check for an extra or missing quad-ring (Figure 9-91).
- 19. Remove clamps or hemostats from the tubing.
- 20. Press SYS HOME.
- 21. Prime as follows:
 - (a) From the MASTER Screen, press **F4 SPECIAL FUNCTION**.
 - (b) Cursor and SELECT 1. Prime or type 1 and ENTER.
 - (c) Cursor and SELECT Wash Solution, Ratio Pump, Electrolyte Reference Flow Cell and Electrolyte Reference Ratio Pump.
 - (d) Press F1 START PRIME.
 - (e) Operator is prompted to enter the number of prime cycles. Type 10 and press ENTER. The display indicates the number of prime remaining.
- 22. Reinstall the flow cell cover and secure the captive screw. Be careful not to pinch tubing.



- 1 Quad Ring
- 2 Potassium Tip
- 3 O-ring
- 4 Electrode Body
- 5 Retainer

Figure 9-91. Potassium Electrode

9.7.4 Replace Calcium Electrode Tip

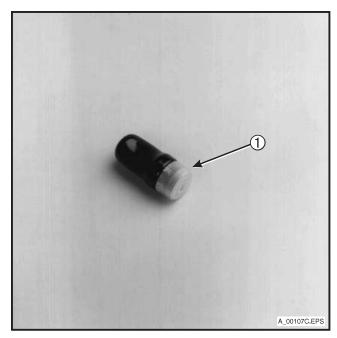
NOTE

Potassium and Calcium Electrode Tip Replacement procedures are identical, but each procedure is listed separately for easy reference. You may perform tip replacement for potassium and calcium simultaneously by following either procedure.

- 1. Prepare soaking solution as follows:
 - (a) Combine one part concentrated Electrolyte Buffer with four parts wash solution. Mix well.
 - (b) Combine one part Electrolyte Reference Reagent with 19 parts of the diluted Electrolyte Buffer (from Step 1a). Mix well.
 - (c) Pour the soaking solution into small beaker or glass container to a depth not to exceed two inches (50 mm).
- Unpack a new calcium electrode tip (P/N 467769). Very carefully remove the knurled protective cap from membrane end of tip assembly. Verify that the black protective cover on the internal threaded connector end of tip assembly is in place (Figure 9-92).
- 3. Lower assembly with the membrane facing down into the soaking solution until it floats (Figure 9-93). For maximum initial operational stability, the ideal soaking time is 24 hours. The minimum required time is one hour.

NOTE

If maximum soaking time is not available, the new electrode may require a few hours of operation to achieve complete electrical stability. During this period of time, more frequent calibration than normal may be required in response to system error messages. Assay results will not be compromised during this time.



1 - Protective Cap

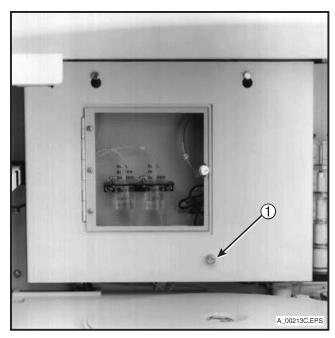
Figure 9-92. Calcium Electrode Tip



Figure 9-93. Soaking the Electrode Tip

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- After soaking is completed, remove the tip from the soaking solution and dry sides using a lintless tissue. DO NOT touch electrode tip.
- Remove the black protective cover from the calcium tip. Check for the presence of moisture. Remove any moisture using lintless tissue.
- 6. Remove the flow cell cover by removing the retaining screw located at the bottom of the cover (Figure 9-94). Grasp the flow cell cover and carefully lift it up and over the two guide screws at the top. Set cover aside for later reinstallation.
- From the Special Functions screen, cursor and SELECT 6. Maintenance Procedures and press ENTER, or type 6 and press ENTER.
- 8. From the maintenance Procedures screen, cursor and **SELECT** 9. Prevent Autopriming and press **ENTER**, or type **9** and press **ENTER**.
- 9. Disconnect the calcium electrode cable (Figure 9-95), being careful not to bend connector pin.



1 - Retaining Screw

Figure 9-94. Flow Cell Cover

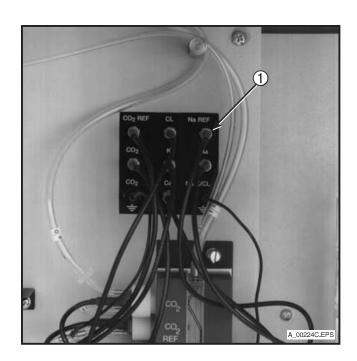
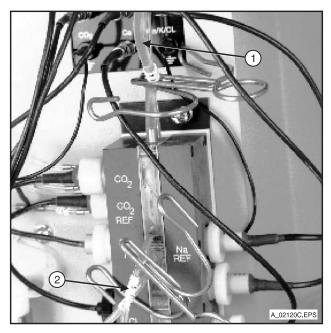


Figure 9-95. Electrode Cable Connectors

- 10. Using a tube clamp or hemostat, securely clamp the TOP FRONT electrolyte drain tubing (line #71) approximately one inch (25 mm) from the top of the flow cell (Figure 9-96). This will prevent the back flow of reagent into the flow cell.
- 11. Using another tube clamp, clamp off the FRONT TOP CO₂ Acid tubing (line #57) on the front of the flow cell as close to the connector as possible (Figure 9-96). This will prevent acid flow into the flow cell.

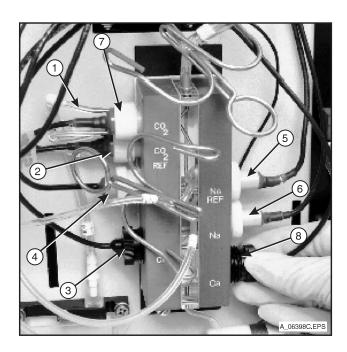
DO NOT disconnect any of the reagent lines attached to the flow cell or remove tubing from flow cell solenoid valve.

- Locate the calcium electrode (Figure 9-97). Remove electrode by turning the electrode retaining nut counterclockwise.
- 13. Remove the retainer nut from OLD electrode.



1 - Line #71

Figure 9-96. Flow Cell Lines #71 and #57 Clamped

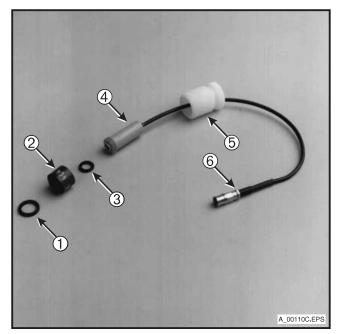


- 1 CO₂ Electrode
- 2 CO₂ Reference Electrode
- 3 CL Electrode
- 4 K Electrode
- 5 Na Reference Electrode
- 6 Na Electrode
- 7 Retainer nut
- 8 Ca Electrode

Figure 9-97. Electrode Placement in the Flow Cell

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- 14. Remove the quad-ring from the tip of the OLD electrode. Inspect the electrode port if the quad-ring is not on the electrode (Figure 9-98). Discard quad-ring.
- Unscrew the OLD tip from the electrode assembly and remove the Oring. Discard the O-ring and the OLD electrode tip.
- Install a new O-ring on the PRE-SOAKED calcium electrode tip and screw onto electrode body.
- 17. Install the NEW quad-ring on the tip of the NEW electrode.
- 18. Using EXTREME CAUTION, thoroughly dry the electrode port with lintless tissue. DO NOT pack tissue into port as damage to the internal wire will occur, thus adversely affecting performance.
- Replace retainer nut on the calcium electrode and insert new electrode into electrode port. Turn electrode retainer nut until finger-tight.
- 20. To test for proper seating of electrode, gently pull on electrode body (Figure 9-99). The electrode assembly should not move. If electrode moves, remove it and install it once again. Check for an extra or missing quad-ring if installation is difficult.
- 21. Reconnect electrode cable to the appropriate terminal (Figure 9-95), being careful not to bend connecting pin.
- 22. Remove hemostats or tube clamps from the tubing (Figure 9-96).
- 23. Press **PREV SCREEN** two (2) times to return to the Special Functions screen.



- 1 Quad-Ring
- 2 Electrode Tip
- 3 O-Ring
- 4 Electrode Body
- 5 Retainer Nut
- 6 Electrode Cable and Connector

Figure 9-98. Removing/Replacing Quad-ring from Calcium Electrode

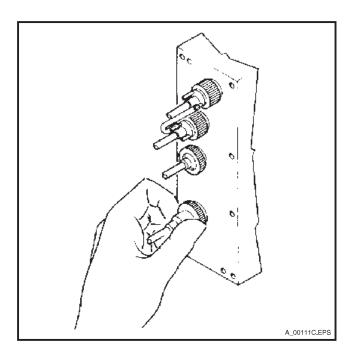


Figure 9-99. Testing for Proper Seating of Calcium Electrode

- 24. Prime electrolyte buffer and CO₂ Acid reagent three times. Program system as follows:
 - (a) From the special Function Screen, cursor and SELECT 1. PRIME and press ENTER, or type 1 and press ENTER.
 - (b) Cursor and **SELECT** Ratio Pump and press **F1 START PRIME**.
 - (c) Type 3 and press ENTER for the number of CX3 prime cycles. Prime Screen will then indicate the number of primes remaining. The prime cycles are completed when the System Status displays Standby.
 - (d) While system is priming, observe flow cell for leaks. Stop the priming if any leaks are noticed and correct the problem.
- 25. Reinstall flow cell cover. Be careful not to pinch tubing.
- 26. Calibrate calcium prior to assaying samples. (Reference drift for calcium may be observed during the first 4 6 hours after calcium replacement. Results will not be compromised. Recalibrating calcium during this time period will help stabilize the calcium electrode.)

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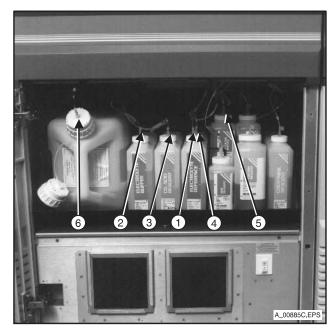
9.7.5 Clean Electrolyte Drain (CX7 Users Only)

- 1. Remove the flow cell cover as follows:
 - (a) Loosen the captive screw at the bottom of the flow cell cover (Figure 9-94).
 - (b) Grasp the flow cell cover.
 - (c) Carefully lift up and over the two fixed guide screws.
 - (d) Set the cover aside for later reinstallation.
- 2. Open CX3 reagent compartment door.
- 3. Remove reagent lines #2, #4, #6, #81, #83, and #34 from the reagent bottles and the wash solution. (Figure 9-100).

NOTE

DO NOT remove the large drain line #82 from the alkaline buffer reagent bottle. This is a return line and removing it could cause a reagent spill when the system is primed.

- 4. Prime as follows:
 - (a) From the MASTER Screen, press F4 SPECIAL FUNCTION.
 - (b) Cursor and SELECT 1. Prime or type 1 and ENTER.
 - (c) Cursor and SELECT Wash Solution, Ratio Pump, Electrolyte Reference Flow Cell and Electrolyte Reference Ratio Pump.
 - (d) Press F1 START PRIME.
 - (e) Operator is prompted to enter number of prime cycles. Type 30 and press ENTER. The display indicates the number of primes remaining. This will evacuate the reagent lines.



- 1 Line #2 Electrolyte Reference
- 2 Line #4 Electrolyte Buffer
- 3 Line #6 CO2 Acid Reagent
- 4 Line #83 Electrolyte Reference
- 5 Line #81 Alkaline Buffer
- 6 Line #34 CX3 Wash Solution

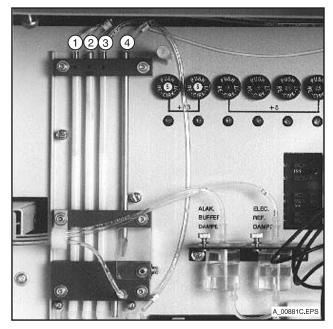
Figure 9-100. CX3 Reagent Compartment

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- 5. Prevent the system from autopriming as follows:
 - (a) From the MASTER Screen, press **F4 SPECIAL FUNC-TIONS**.
 - (b) Cursor and **SELECT** 6. Maintenance or type **6** and **ENTER**.
 - (c) Cursor and **SELECT** 9. CX3 Prevent Autoprime or type **9** and **ENTER**.
- 6. Remove lines #79, #71, #45 and #80 from the top of the drain assembly (Figure 9-101). Carefully place aside for later reinstallation.

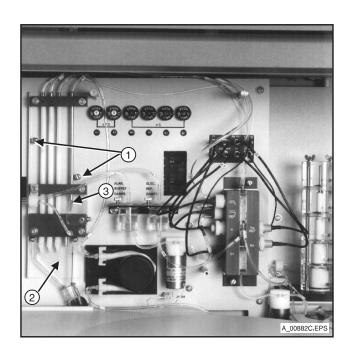
When removing the large drain tubing from the base of drain assembly (Step 8), DO NOT allow the tubing to slide down into the body of the instrument as retrieval may be difficult.

- 7. Loosen the two mounting screws and remove the drain assembly (Figure 9-102).
- 8. Remove the large drain line, #31, from the bottom of the drain assembly.



- 1 Line #79
- 2 Line #71
- 3 Line #45
- 4 Line #80

Figure 9-101. CX3 Drain Assembly



- 1 Mounting Screws
- 2 Funnel
- 3 Splash shield

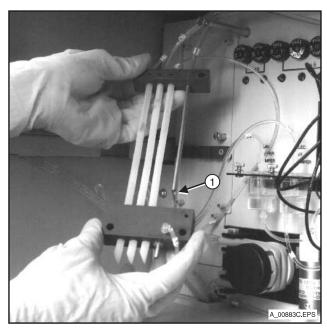
Figure 9-102. CX3 Drain Assembly

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- 9. Clean drain assembly as follows:
 - (a) Disassemble drain assembly (Figure 9-103):

Keep the washers and screws in a safe area for later reinstallation.

- Unscrew and remove the two Phillips-head screws from the lower end of the drain assembly.
- ii. Remove the drain funnel by sliding it off the two screwguides. Set the funnel aside for later cleaning.
- iii. Unscrew and remove the two short socket-head screws that secure the plastic splash shield in place. (Use the 7/64-inch sockethead wrench [P/N 817304] from the CX3 Maintenance Kit.)
- iv. Remove the plastic splash shield and set aside for later cleaning.
- v. Unscrew and remove the remaining six long sockethead screws from the drain assembly. The bottom screw on the left also secures a plastic tubing holder to the assembly; remove this and set aside for later reinstallation.
- vi. Lift the top portion of the middle gray holder off the assembly and set aside for later cleaning.
- vii. Simultaneously, lift the top and bottom gray holders off the assembly back panel and set on flat surface.
- viii. Slide the bottom gray holder off the bottoms of the plastic straws.
- ix. Slide the three plastic straws off of the metal guide-tubes on the top gray holder.



1 - Wire mesh

Figure 9-103. Disassembling CX3 Drain

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- x. Carefully remove the wire mesh drip guides from the metal guide tubes.
- (b) Clean the pieces of the drain assembly as follows:
 - Clean all pieces of the assembly with distilled or deionized water and lintless tissue.
 - ii. Clean the three plastic straws with distilled or deionized water and cotton applicator swabs.

If drain assembly needs additional cleaning, use a disinfectant soap to wash and then rinse thoroughly with distilled or deionized water.

- iii. Dry all pieces with lintless tissue.
- (c) Reassemble drain assembly as follows:
 - Replace wire mesh drip guides into lower openings of metal tubes from which they were removed (the right and the third from right guide tubes).

NOTE

Verify correct orientation of wire mesh guides. (The bevels of the wire mesh drip guides should be open toward the right.)

- ii. Replace the three plastic straws over the metal guide tubes attached to the top gray holder.
- iii. Slide the bottom gray holder over the lower end of the plastic straws.
- iv. Simultaneously lift the top and bottom gray holders onto the drain assembly back panel and lower over the appropriate screw guides.
- v. Replace the middle gray holder across the plastic straws.
- vi. Replace and tighten the top two socket-head screws in the top gray holder to secure the holder in place.
- vii. Replace and tighten the bottom two socket-head screws in the bottom gray holder to secure the holder in place.

NOTE

Verify that the tops of the plastic straws are still securely in the sockets of the top gray holder. (The bevels of the straws should be open toward the right.)

- viii. Replace and tighten the two sockethead screws in the middle gray holder to secure the holder in place. Make sure to secure the plastic tubing holder to the drain assembly by attaching it with the left screw on the middle section.
- ix. Replace the plastic splash shield and secure in place with the two short socket-head screws.
- x. Replace the drain funnel (the tubing leaving the funnel should angle toward the right) (Refer to Figure 9-102) and secure in place with the two Phillips-head screws.
- 10. Reinstall the drain assembly on the system.
- 11. Reconnect drain lines #79, #71, #45, and #80 to the top of the assembly and the large drain tubing, #31, to the bottom. (Figure 9-101).
- 12. Reconnect the reagent lines as follows:
 - #2 Electrolyte Reference
 - #4 Electrolyte Buffer
 - #6 CO₂ Acid Reagent
 - #83 Electrolyte Reference
 - #81 Alkaline Buffer
 - #34 Wash Solution
- 13. Press PREV SCREEN or MASTER SCREEN.
- Close reagent compartment cover.
- 15. Prime as follows:
 - (a) From the MASTER Screen, press **F4 SPECIAL FUNCTION**.
 - (b) Cursor and SELECT 1. Prime or type 1 and ENTER.
 - (c) Cursor and SELECT all CX3 Chemistries, Wash Solution, Ratio Pump, Electrolyte Reference Flow Cell, Electrolyte Reference Ratio Pump and Alkaline Buffer.
 - (d) Press F1 START PRIME.

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- (e) Operator is prompted to enter the number of prime cycles. Type 30 and press ENTER. The display indicates the number of primes remaining.
- (f) Observe for leaks. Stop the prime if any occur and correct the problem before continuing.
- 16. Reinstall the flow cell cover and secure the captive screw. Be careful not to pinch the tubing.

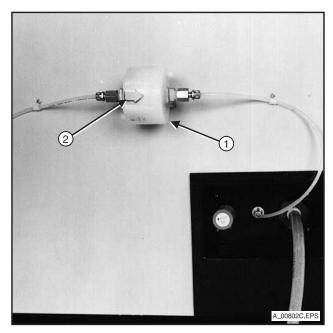
9.7.6 Replace Inlet Water Filter

- 1. Turn off input water at source.
- 2. Release the pressure from the hydropneumatics unit by:
 - (a) From the MASTER Screen, press F4 SPECIAL FUNCTION.
 - (b) Cursor and SELECT 6. Maintenance Procedures or type 6 and ENTER.
 - (c) Cursor and SELECT 4. Hydropneumatic System Shutdown or type 4 and ENTER.
- 3. Locate the inlet water filter in its bracket on the back of the instrument (Figure 9-104).
- 4. Place a suitable container under the filter to catch any residual water and remove the input and output water lines from either side.

NOTE

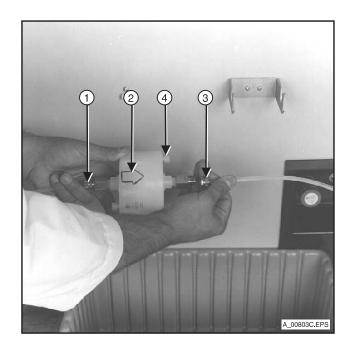
Teflon tape should be applied to the input and output line fittings before proceeding to Steps 5 and 6.

- Install the new filter so that the input water line is connected to the end of the filter opposite the direction of flow arrow on the side of the filter (Figure 9-105).
- 6. The line leading from the filter to the system should be connected to the end of the filter pointed to by the arrow (Figure 9-105).
- 7. Make sure all connections are tight.



- 1 Inlet Water Filter
- 2 Direction-of-Flow Arrow

Figure 9-104. Inlet Water Filter



- 1 Input Water Line
- 2 Direction-of-Flow Arrow
- 3 Output Water Line (To Instrument)
- 4 Air Bleed Valve

Figure 9-105. Inlet Water Filter Replacement

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8. Reinstall the filter into the holding bracket on the back of the instrument.

NOTE

Orient the white filter so air bleed valve is in upright position. Remove cap on bleed valve. Slowly turn water partially on. Allow air to bleed out of the system by letting some water fall into the receptacle. Turn water off. Tighten cap on bleed valve.

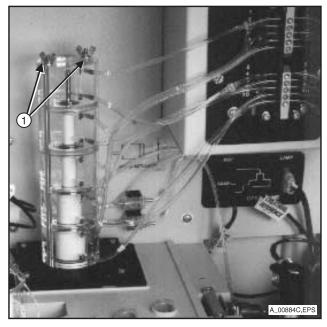
- 9. Turn the source water on and check the filter fittings for leaks.
- 10. If leaks occur, repeat Steps 4 through9.
- 11. Press **PREV SCREEN** or **MASTER SCREEN** to exit procedure and restart hydropneumatic unit.

CX3:

9.7.7 Replace Five-stage Ratio Pump Quad-rings (CX7 Users Only)

A ratio pump maintenance kit (P/N 443004) is needed to complete this procedure.

1. Open CX3 reagent compartment door.



1 - Wing Nuts

Figure 9-106. Ratio Pump

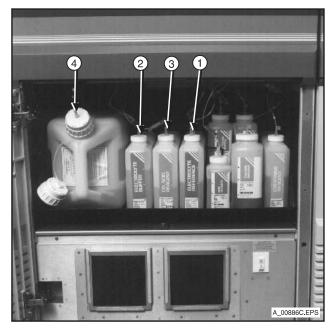
- 2. Remove reagent lines labeled #2, #4, #6, and #34 from the wash solution and reagent bottles (Figure 9-107).
- 3. Prime as follows:
 - (a) From the MASTER Screen, press F4 SPECIAL FUNCTION.
 - (b) Cursor and SELECT 1. Prime or type 1 and ENTER.
 - (c) Cursor and **SELECT** Wash Solution, Ratio Pump, and Electrolyte Reference Ratio Pump.
 - (d) Press F1 START PRIME.
 - (e) Operator is prompted to enter the number of prime cycles. Type 20 and press ENTER. The display indicates the number of primes remaining. This will evacuate all of the lines.
- When priming is complete, prevent the system from autopriming as follows:
 - (a) Press **F4 SPECIAL FUNC-TIONS**.
 - (b) Cursor and **SELECT** 6. Maintenance or type **6** and **ENTER**.
 - (c) Cursor and **SELECT** 9. CX3 Prevent Autoprime or type **9** and **ENTER**.
- Disconnect lines #1 through #10 from ratio pump. Hold top of pump while gently twisting to remove each line (Figure 9-108).

CAUTION

Care must be taken when removing or replacing lines 5 and 6 from the ratio pump, as damage may occur to the plastic fittings.

NOTE

This procedure may be performed with the ratio pump in place on the instrument, or with the ratio pump removed from the instrument. If the ratio pump is to be removed, refer to the Diagnostics and Troubleshooting Guide (Section 4) for complete instructions.



- 1 Line #2 Electrolyte Reference
- 2 Line #4 Electrolyte Buffer
- 3 Line #6 CO₂ Acid Reagent
- 4 Line #34 CX3 Wash Solution

Figure 9-107. CX3 Reagent Compartment

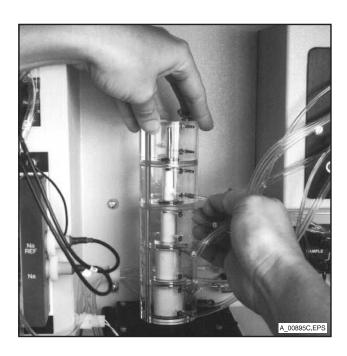


Figure 9-108. Disconnect Ratio Pump Lines

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- 6. Unscrew and remove the two wing nuts from the top of the assembly (Figure 9-108).
- 7. Lift cylinders one at a time from the ratio pump (Figure 9-109) and lay them down in a row in the order removed (refer to Figure 9-110).

For best results, keep each cylinder with its respective O-rings and quad-rings in a separate section of the work area to simplify identification and location of the new O-rings and quad-rings.

- 8. Using lintless tissue, wipe the entire piston dry taking care not to scratch the surface of the piston.
- 9. Remove and discard quad-rings from cylinders.
- 10. Wipe inside and outside of each cylinder using a dry, lintless tissue.
- 11. With your finger tips, apply a LIGHT (almost invisible) coating of Silicone Compound (P/N 879049) to each new quad-ring. Avoid heavy coat of lubricant, as this may cause clogged reagent lines.
- 12. Place the appropriate new quad-rings and O-rings (P/N 443004) in each cylinder. Replace the cylinders one at a time (in the reverse order they were removed) on the piston. (Figure 9-110).

CAUTION

Be careful not to twist quadrings during installation, as this could result in reagent leakage or even in ratio pump failure.

 Install and finger-tighten the two wing nuts on top of the ratio pump assembly.

NOTE

If the ratio pump was previously removed, reinstall it according to the instructions in the Diagnostics and Troubleshooting Guide (Section 4).

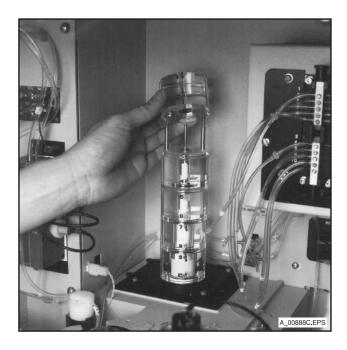
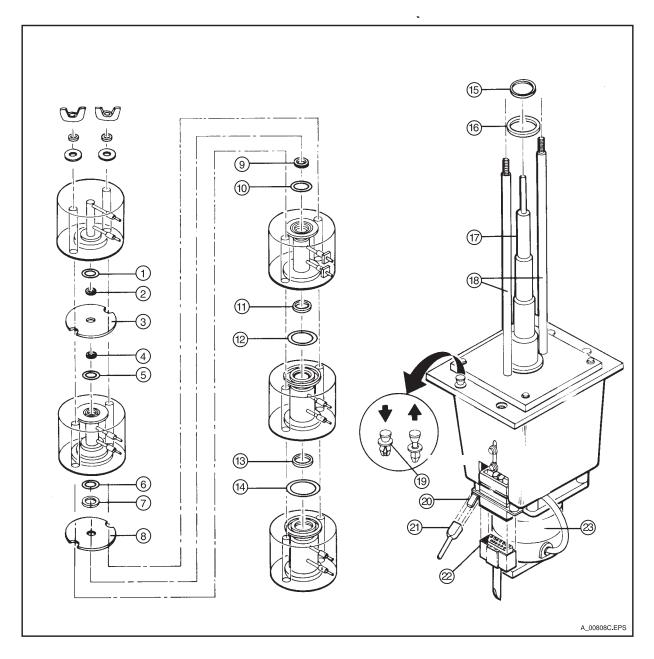


Figure 9-109. Removing Cylinder from Ratio Pump



1 - O-Ring	835051	9 - Quad-Ring	443417	17 - Teflon Bushing 45	50827
2 - Quad-Ring	879025	10 - O-Ring	928555	18 - Alignment Rods	
3 - Retainer	443056	11 - Quad-Ring	443483	19 - Mounting Pins	
4 - Quad-Ring	879025	12 - O-Ring	928167	20 - Ground Lug	
5 - O-Ring	835051	13 - Quad-Ring	883947	21 - Grounding Wire	
6 - O-Ring	928555	14 - O-Ring	888875	22 - 15 Pin "D" Connector	
7 - Quad-Ring	443417	15 - Quad-Ring	883948	23 - Stepper Motor	
8 - Retainer	443057	16 - O-Rina	881792		

Figure 9-110. Disassembled Ratio Pump

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- 14. Reconnect lines #1 through #10 to the matching numbered connections on the ratio pump.
- 15. Verify all lines have remained secure in the pinch valve.
- 16. Press PREV SCREEN or MASTER SCREEN.
- 17. Reconnect reagent lines as follows:

#2 into Electrolyte Reference #4 into Electrolyte Buffer #6 into CO₂ Acid Reagent #34 into Wash Solution

- 18. Close compartment door.
- 19. Prime as follows:
 - (a) From the MASTER Screen, press **F4 SPECIAL FUNCTION**.
 - (b) Cursor and SELECT 1. Prime or type 1 and ENTER.
 - (c) Cursor and **SELECT** wash Solution, Ratio Pump and Electrolyte Reference Ratio Pump.
 - (d) Press F1 START PRIME.
 - (e) Operator is prompted to enter the number of prime cycles. Type 20 and press ENTER. The display indicates the number of primes remaining.
 - (f) While system is priming, observe ratio pump for leaks. Stop priming if any leaks are noticed and correct the problem.

9.8 AS-NEEDED MAINTENANCE PROCEDURES

CX4:

9.8.1 Clean Glass Cuvettes on Reaction Carousel

- Carefully remove all cuvettes from the Reaction Carousel Assembly (Figure 9-111) using the cuvette removal procedure (refer to the Diagnostics and Troubleshooting Guide - Section 4).
- 2. Place cuvettes in a single layer in a shallow container, taking care not to scratch the cuvette glass.
- Prepare a 10% solution of Trace-Klean in deionized water; use the proper protective clothing and gloves when preparing and using the solution.
- 4. Pour into the container an amount of the cleaning solution sufficient to cover the cuvettes. Ensure that no air bubbles are trapped in the cuvettes and that the solution comes in contact with all of the cuvette glass surfaces. Exercise caution to avoid scratching the glass cuvettes.
- 5. Cover the container and let stand for two hours at room temperature.
- 6. Using a poly swab (P/N 758965), clean the inside of the cuvettes.
- 7. Remove the cuvettes and thoroughly rinse with deionized water.
- Use a lintless disposable towel to dry the rinsed cuvettes. Use clean, lintfree gloves when handling the cuvettes.
- 9. Inspect to ensure there are no visible scratches on the optical window surfaces at the bottom 10 mm of the cuvettes. Discard the cuvette if scratches are observed. Also, inspect to ensure there is no lint remaining either in or on the cuvettes.
- Reinstall cuvettes with clear sides exposed through reaction carousel openings.

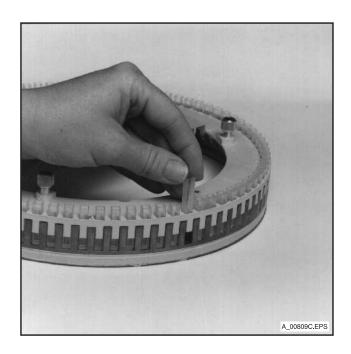


Figure 9-111. Removing Glass Cuvettes

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9.8.2 Decontaminate Sample Sectors

CAUTION

DO NOT autoclave sample sectors.

- 1. Prepare a 10% bleach solution (approximately 0.5% final hypochlorite solution) in deionized water.
- 2. Using a large container or a sink, immerse all sample sectors in the bleach solution.
- 3. Allow the sample sectors to soak at room temperature in the bleach solution for 15 to 20 minutes.
- Remove the sectors and rinse with deionized water or tap water and allow to dry.

NOTE

Repeated decontamination of sectors may result in sector label damage. If label starts to bubble or peel, remove and replace with a new label (Refer to Section 2 of this manual).

9.8.3 Decontaminate CX3 Wash Bottle, CX3 Reagent and Wash Solution Straws, CX4 Reaction Carousel Tub and All External Surfaces

CAUTION

CX7 users must perform steps 1 and 2 of this procedure at least 24-hours prior to performing steps 3-5 because of the time required for outgassing of the CX3 wash solution.

Prepare 70% Isopropanol (IPA) cleaning solution:

- Place 1400 mL of isopropanol in a 2liter bottle. Add 540 mL of deionized water and 60 mL of Physiological Saline (0.85% NaCl) solution. Mix well.
- 2. Clean spare 10-liter CX3 wash bottle and prepare CX3 wash solution:
 - (a) Clean the spare 10-liter CX3 wash bottle with some of the IPA cleaning solution.
 - (b) Rinse wash bottle thoroughly with deionized water.
 - (c) Prepare CX3 wash solution as directed on the wash concentrate bottle.
 - (d) Let stand for 24-hours (to allow outgassing to occur) before installing onto the system in step 4 of this procedure.

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- Clean CX3 10-liter wash bottle, reagent, and CX3 wash solution straws:
 - (a) Open the CX3 reagent compartment door.
 - (b) Remove the CX3 10-liter wash bottle from the system (Figure 9-112). Empty the bottle and clean it with IPA cleaning solution.
 - (c) Rinse bottle, thoroughly, with deionized water and allow to dry completely before storing.
 - (d) Remove all the reagent straws from the reagent bottles. Wipe the exterior of the straws with a lintless tissue.
 - (e) Prime all CX3 Modules with air as follows (catching the return from the alkaline buffer line, #82, in a beaker):
 - From the MASTER Screen, press F4 SPECIAL FUNC-TION.
 - ii. Cursor and **SELECT** 1. PRIME or type **1** and **ENTER**.
 - iii. Cursor and **SELECT** all CX3 Modules.
 - iv. Press F1 START PRIME.
 - v. Operator is prompted to enter the number of prime cycles. Type 5 and press ENTER. The display indicates the number of primes remaining.
 - (f) Place reagent straws and CX3 wash solution straw in a beaker of IPA cleaning solution, and prime all CX3 Modules 30 times (Figure 9-113).
 - (g) Allow the solution to stand for 10 minutes.



1 - CX3 Wash Bottle

Figure 9-112. CX3 Reagent Compartment



Figure 9-113. Place Straws Into Beaker of IPA

4. Prepare the CX3 for use:

- (a) Remove straws from beaker of IPA cleaning solution and prime all CX3 Modules with air 5 times as follows:
 - i. From the Special Functions Screen, cursor and SELECT1. Prime or type 1 and ENTER.
 - ii. Cursor and **SELECT** all CX3 Modules, and chemistries.
 - iii. Press F1 START PRIME.
 - iv. Operator is prompted to enter the number of prime cycles. Type 5 and press ENTER. The display indicates the number of primes remaining.
 - v. Press MASTER SCREEN.
- (b) Prime the Alkaline Buffer reagent an extra 15 times to remove all fluid from the recycle lines.
- (c) Dry the exteriors of the straws with lintless tissue.
- (d) Install the CX3 wash solution (prepared in step 2) on the system.
- (e) Perform maintenance for BUN3 and GLU3 modules.
- (f) Place straws back in reagent bottles and wash bottle and prime all CX3 Modules an additional 5 times.

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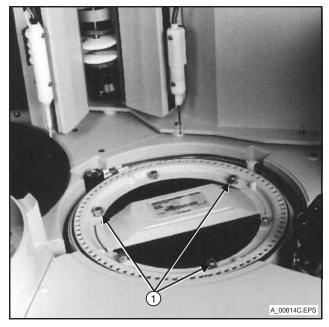
- (g) Perform a reagent load as follows:
 - From the MASTER Screen, press F2 REAGENT LOAD.
 - ii. Press F3 CX3 LOAD.
 - iii. Cursor and **SELECT** all CX3 Modules, and chemistries.
 - iv. Press F4 CONTINUE.
 - v. Press F1 PRIME.
 - vi. When procedure is complete, press MASTER SCREEN.
- (h) Adjust the reagent level percentage to correspond to the current level in the CX3 reagent bottles as follows:
 - From the MASTER Screen, press F2 REAGENT LOAD.
 - ii. Press F3 CX3 LOAD.
 - iii. Press F2 ADJUST VOL-UMES.
 - iv. Enter the correct volume for each reagent.
 - v. Press **PREV SCREEN** to exit the CX3 Volume Adjust window.
- (i) Allow reagent to sit in lines for 10 minutes to equilibrate electrodes.
- 5. When procedure is complete, calibrate all CX3 chemistries.

Decontaminate External Surface Areas:

- 6. Using a 10% bleach solution, thoroughly wipe the components and assemblies indicated below:
 - · Reagent Probe and Mixer
 - Sample Probe and Mixer
 - Exterior Sample Carousel
 - Autoload Buttons and surrounding front panel
 - Autoloader Tray and Transfer Carousel
 - Cuvette Reaction Carousel Surface
 - Reagent Compartment Door

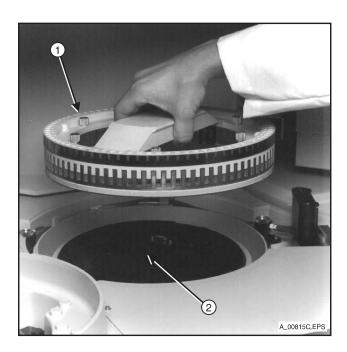
Decontaminate the Reaction Carousel Tub:

- 7. Remove reaction carousel cover. (Refer to Paragraph 9.8.10.)
- 8. Remove slotted thumbscrews to release cuvette wash station. Lift unit up and set aside.
- 9. Loosen the three captive recessed thumbscrews adjacent to cuvette numbers 8, 34, and 61 (Figure 9-114).
- 10. Grasp the reaction carousel assembly handle and lift straight up (Figure 9-115). Avoid bumping the three carousel sensors located to the front of the assembly. Place assembly on a flat surface.
- 11. Wipe the tub clean with a 10% bleach solution.



1 - Captive Thumbscrews

Figure 9-114. Reaction Carousel

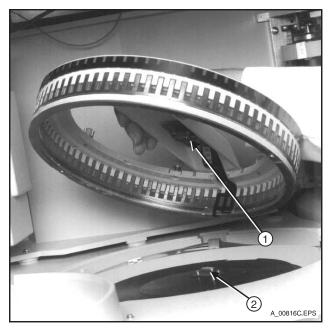


- 1 Reaction Carousel Assembly
- 2 Tub

Figure 9-115. Removing Reaction Carousel

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- 12. Reinstall the reaction carousel assembly so that the 9-pin connector on the underside of the assembly lines up with its receptacle (Figure 9-116).
- 13. Gently lower the carousel assembly into position. Finger-tighten thumb-screws.
- 14. Replace reaction carousel cover.



- 1 9 Pin Connector
- 2 Receptacle

Figure 9-116. Reaction Carousel

9.8.4 Replace Sample and Reagent Mixer Paddle

- Remove cuvette wash station, autoloader, sample carousel and reaction carousel covers. (Refer to Paragraph 9.8.10, steps 1-4.)
- 2. Enter the Diagnostics Screen by programming the system as follows:
 - (a) From the MASTER Screen, press F4 SPECIAL FUNCTION.
 - (b) Cursor and SELECT 3. Diagnostics/Alignment or type 3 and ENTER.
 - (c) Press Y.
- 3. From the diagnostics MAIN MENU Screen:
 - (a) Press F2 SETUP OPTIONS to select operation mode.
 - (b) Cursor and SELECT ALIGN-MENT Mode.
 - (c) Press PREV SCREEN to return to the diagnostics MAIN MENU Screen.
 - (d) Cursor and SELECT the appropriate functional area: 7. Sample System (for sample mixer replacement) or 8. Reagent System (for reagent mixer replacement).
 - (e) Press **SELECT**.
 - (f) Cursor and SELECT 2. Mixer Rotary Alignment or type 2 and ENTER; then press Y.

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 When the screen displays Procedural Steps, carefully move the probe crane assembly aside for easy access to the mixer assembly.

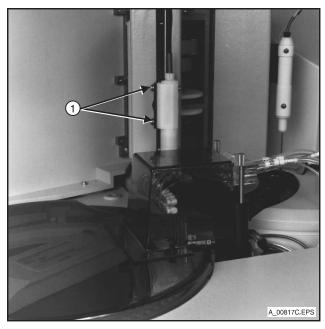
NOTE

Once the functional area in diagnostics is accessed, all motors to the crane assembly selected should move freely without resistance. Should you experience any difficulties, call your local Beckman office for assistance (North American Customers, call 1-800-854-3633).

NOTE

Disregard instructions on the screen at this Step. Rotary alignment should not be necessary at this time.

- 5. Thoroughly wipe the mixer paddle to be replaced using a lintless tissue soaked with 70% isopropanol.
- Remove the two Phillips-head screws holding the mixer assembly to the mixer crane. Set aside (Figure 9-117).
- Firmly hold the mixer assembly in one hand. Using a needle-nose pliers, grasp the bottom of the metal shaft near the collar. Be careful not to damage the gold coating on the mixer paddle. (Figure 9-118).



1 - Mounting Screws

Figure 9-117. Mixer Assembly

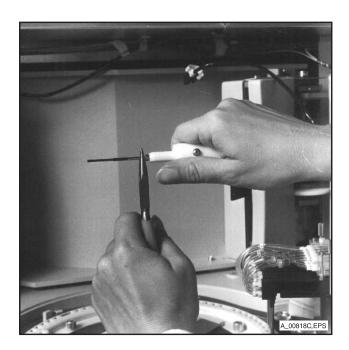


Figure 9-118. Use Pliers to Grasp Bottom of Metal Shaft

- 8. While holding the pliers in place, separate the mixer paddle from the assembly by pressing your thumb against the pliers. (Figure 9-119)
- 9. Remove the paddle, being careful not to lose the bearing cup.

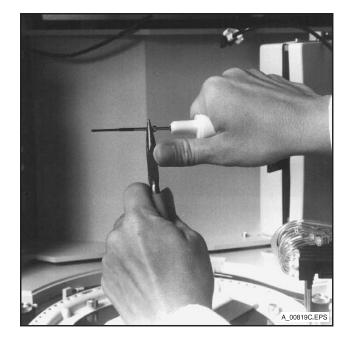


Figure 9-119. Separate the Mixer Paddle from the Assembly

10. Replace with the new paddle mixer by engaging the metal shaft of the mixer into the assembly. (Figure 9-120)

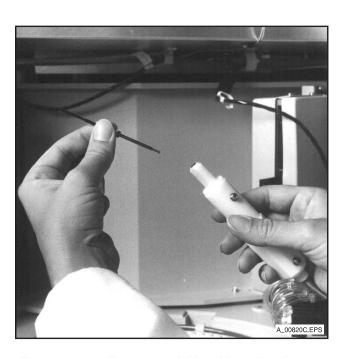


Figure 9-120. Replace with New Mixer Paddle

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- 11. Snap the new paddle mixer into place. (Figure 9-121)
- 12. Reattach the mixer assembly to the mixer crane using the two Phillipshead screws. Tighten securely.
- 13. To return to the diagnostics MAIN MENU Screen, program the system as follows:
 - (a) Press PREV SCREEN.
 - (b) Press Y.
 - (c) Press PREV SCREEN.
 - (d) Press **F2 SETUP OPTIONS** to select operation mode.
 - (e) Press **SELECT** to enter into the extended Mode.
 - (f) Press PREV SCREEN.
- 14. Choose the appropriate functional area.
- 15. Press SELECT.
- Cursor and SELECT 2. Mixer or typeand ENTER.
- 17. Press F1 CONTINUE.
- 18. When the system is ready, press **F1 ROTARY MOTOR**.
- 19. When the system is ready, press **ENTER** to move mixer arm over the cuvette position.
- 20. Press **F1 VERTICAL POWER** to relieve power to vertical motor.

CAUTION

Pressing the down arrow key releases power to the mixer crane vertical motor and allows the operator to center the mixer in the cuvette. Cuvette breakage may occur if mixer assembly is not gently lowered into cuvette.

21. Center mixer between front and rear walls of cuvette.

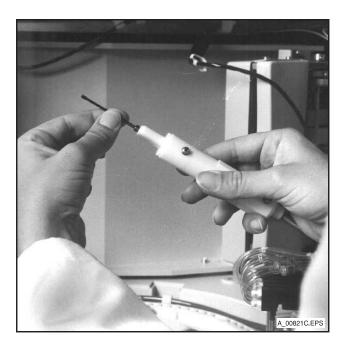


Figure 9-121. Snap the Mixer Paddle Into Place

- 22. Tighten Phillips-head screws securely onto mixer mounting bracket. Observe that mixer remains centered in cuvette.
- 23. Press **ENTER** to step through mixer positions. Verify that mixer is centered in cuvette.
- 24. Press **F8 DIAG MENU** to return to the diagnostics MAIN MENU Screen.
- 25. Press F2 SETUP OPTIONS.
- 26. Press **SELECT** to enter into the ALIGNMENT Mode.
- 27. Press **PREV SCREEN** to return to the diagnostics MAIN MENU Screen.
- 28. Choose the appropriate functional area.
- 29. Press **SELECT**.
- 30. Using the arrow keys, toggle to 8. Mixer Height Adjustment. Press **SELECT**.
- 31. Press Y.
- 32. Clear area around probe and mixer.
- 33. Press ENTER.
- 34. Manually lower mixer as far as possible.
- 35. Press ENTER.
- 36. Press **F8 DIAG MENU** to enter the diagnostics MAIN MENU Screen.
- 37. Press **PREV SCREEN** to exit diagnostics and return to the OPERATING PROGRAM MASTER Screen.
- 38. Replace covers (refer to paragraph 9.8.10).

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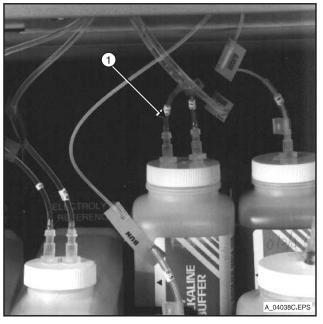
9.8.5 Replace CO₂ Measuring Electrode Membrane (CX7 Users Only)

CO₂ Measuring Electrode Removal:

- Open CX3 reagent compartment door.
- Remove reagent line (#81) from the alkaline buffer reagent bottle (Figure 9-122). DO NOT remove the return line (#82) from the alkaline buffer reagent bottle, as this could cause a reagent spill when the system is primed.

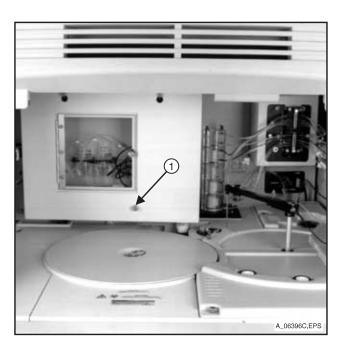
3. Prime as follows:

- (a) From the MASTER Screen, press F4 SPECIAL FUNCTION.
- (b) Cursor and SELECT 1. Prime or type 1 and ENTER.
- (c) Cursor and **SELECT** Alkaline Buffer.
- (d) Press F1 START PRIME.
- (e) Operator is prompted to enter the number of prime cycles. Type 10 and press ENTER. The display indicates the number of primes remaining.
- 4. Remove the flow cell cover as follows:
 - (a) Loosen the captive screw at the bottom of the flow cell cover (Figure 9-123).
 - (b) Grasp the flow cell cover.
 - (c) Carefully lift up and over the two fixed guide screws.
 - (d) Set the cover aside for later reinstallation.



1 - Reagent Line #81

Figure 9-122. Remove Reagent Line #81



1 - Captive screw

Figure 9-123. Removing Flow Cell Cover

- 5. Prevent the system from autopriming as follows:
 - (a) Press **F4 SPECIAL FUNC-TIONS**.
 - (b) Cursor and **SELECT** 6. Maintenance or type **6** and **ENTER**.
 - (c) Cursor and **SELECT** 9. CX3 Prevent Autoprime or type 9 and **ENTER**.
- 6. Disconnect the CO₂ Measuring Electrode cable (Figure 9-124).

7.

- (a) Using a tube clamp or hemostat, securely clamp the TOP FRONT electrolyte drain tubing (line #71) approximately one inch (25 mm) from the top of the flow cell. This will prevent the back flow of reagent into the flow cell (Figure 9-125).
- (b) Using another tube clamp or hemostat, securely clamp off the FRONT TOP CO₂ Acid tubing (line #57) on the front of the flow cell as close to the connector as possible. (Figure 9-125) This will prevent acid flow into the flow cell.

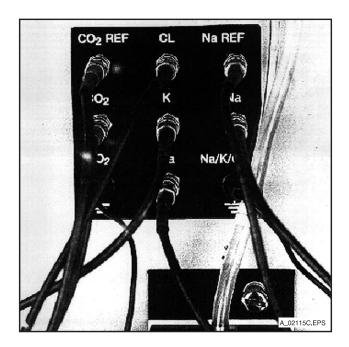
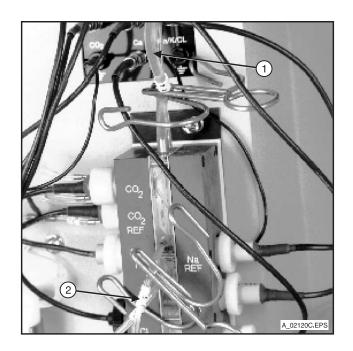


Figure 9-124. Disconnect CO₂ Measuring Electrode Cable

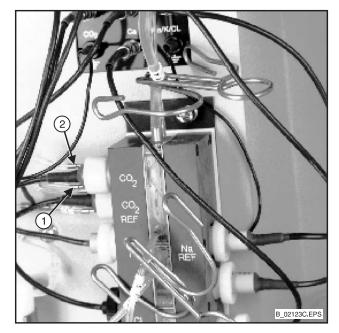


- 1 Line #71
- 2 Line #57

Figure 9-125. Flow Cell Lines #71 and #57 Clamped

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 Locate the CO₂ measuring electrode. Disconnect reagent lines #78 and #80 from the electrode (Figure 9-126). Remove electrode by turning the electrode retainer nut counterclockwise (Figure 9-127).

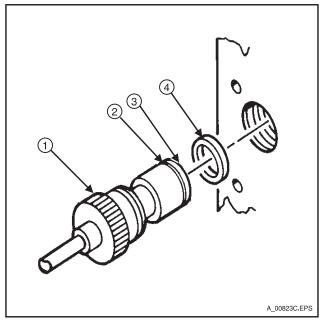


- 1 Line #78
- 2 Line #80

Figure 9-126. Disconnect Reagent Lines #78 and #80

CO₂ Measuring Electrode Membrane Replacement:

- 9. Remove electrode retainer nut, then remove the membrane as follows:
 - (a) Separate the membrane retainer assembly from the electrode (Figure 9-127).
 - (b) Remove the quad-ring from the retainer. Inspect the electrode port if the quad-ring is not on the electrode.
 - (c) Separate the membrane retainer from the membrane clamp and pull apart. Discard the used membrane.



- 1 Retainer Nut
- 2 Membrane Clamp
- 3 Membrane Retainer
- 4 Quad-Ring

Figure 9-127. CO₂ Measuring Electrode

10. Using tweezers, remove new membrane (P/N 661750) from the package in the CX3 Maintenance Kit. Rinse the membrane thoroughly in deionized water to remove all traces of dry powder. Dry the membrane using lintless tissue (Figure 9-128).

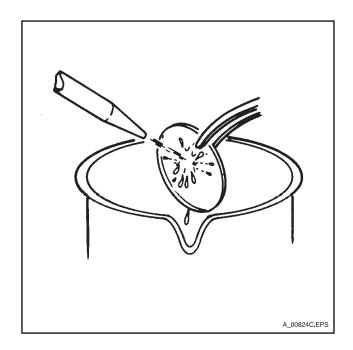
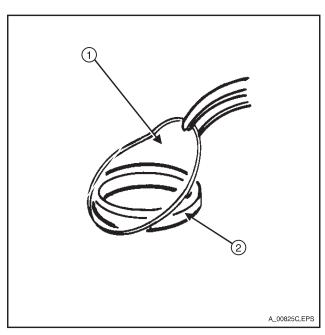


Figure 9-128. Rinse the Membrane in Deionized Water

11. Place the membrane clamp on a flat surface. Using tweezers, carefully center the membrane on top of the membrane clamp (Figure 9-129).

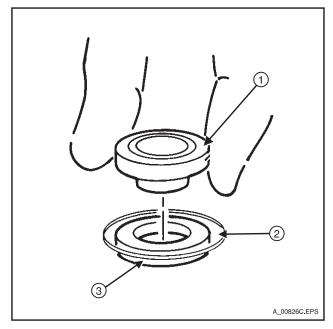


- 1 Membrane
- 2 Clamp

Figure 9-129. CO_2 Membrane Placement

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12. Center the membrane retainer over the membrane clamp. Press the membrane retainer into the clamp, thus securing the membrane (Figure 9-130).



- 1 Retainer
- 2 Membrane
- 3 Clamp

Figure 9-130. Securing the CO₂ Membrane

13. Place the retainer assembly upside down on the work surface so the clamp is on top and retainer on bottom. Grasp the electrode carefully and press it firmly against the membrane and into the membrane clamp (Figure 9-131).

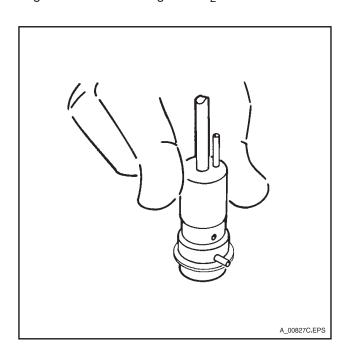


Figure 9-131. Press Electrode Against Membrane and into Clamp

14. Inspect the membrane to verify that it is not broken and is centered properly with no uneven edges protruding. If membrane is not centered correctly or is damaged, repeat Steps 9 through 13 (Figure 9-132).

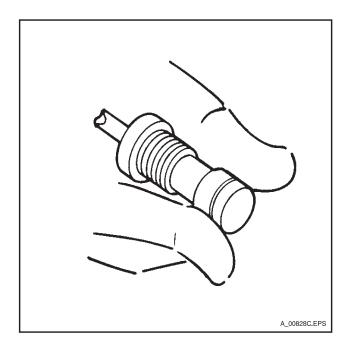


Figure 9-132. Inspecting the CO₂ Membrane

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15. Reinstall the quad-ring onto the membrane retainer. When installed, the quad-ring must be on the very end of the CO₂ electrode. This ensures a proper fluid seal when the electrode is installed in the flow cell (Figure 9-133).

CAUTION

Do not touch membrane surface when installing the quadring.

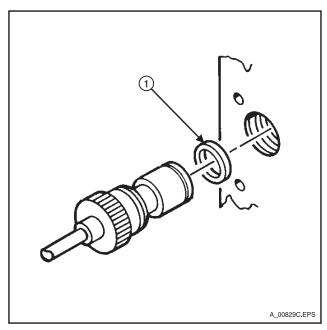
CO₂ Measuring Electrode Replacement:

 Using a lintless tissue, carefully and thoroughly dry the electrode assembly and electrode port.

NOTE

Electrode and electrode port must be completely dry before reinstalling electrode.

- Insert the CO₂ electrode onto the electrode port being careful to align key pin on electrode with keyway in the electrode port.
- 18. Insert retainer nut and turn until finger-tight.
- 19. To test for proper seating of electrode, gently pull on electrode body. The electrode assembly should not move. If the electrode moves, remove it and try to install it once again. If installation is difficult, check for an extra or missing quad-ring (Figure 9-134).
- 20. Reconnect tubing lines #78 and #80 to the electrode.
- 21. Reconnect reagent line #81 to the alkaline buffer reagent bottle.
- 22. Reposition flow cell on mounting panel. Tighten the two retaining screws.
- 23. Reconnect electrode cable to the appropriate connector.
- 24. Remove tube clamps or hemostats from (lines #71 and #57) of tubing.



1 - Quad Ring

Figure 9-133. Reinstallation of Quad-Ring

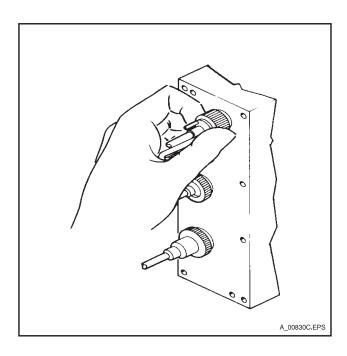


Figure 9-134. Testing CO₂ Electrode for Proper Seating

25. Press **PREV SCREEN** or **MASTER SCREEN**.

26. Prime as follows:

- (a) From the MASTER Screen, press F4 SPECIAL FUNCTION.
- (b) Cursor and **SELECT** 1. Prime or type **1** and **ENTER**.
- (c) Cursor and **SELECT** Alkaline Buffer.
- (d) Press **F1 START PRIME**.
- (e) Operator is prompted to enter the number of prime cycles. Type 10 and press ENTER. The display indicates the number of primes remaining.
- (f) While system is priming, observe flow cell for leaks. Stop priming if any leaks are noticed.
- 27. Reinstall the flow cell cover and secure the captive screw. Be careful not to pinch the tubing.

9.8.6 Replace Quad-ring in Electrolyte Injection Cup (CX7 Users Only)

- 1. Remove both shields over the chemistry reaction cups as follows (Figure 9-40):
 - (a) Unscrew all four retaining nuts and three thumb screws.
 - (b) Remove the front shield located over the BUN, glucose and calcium or total protein chemistry reaction cups.

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- (c) Program the system as follows:
 - From the MASTER Screen, press F4 SPECIAL FUNC-TIONS.
 - ii. Cursor and SELECT 6. Maintenance Procedures or type 6 and ENTER.
 - iii. Cursor and SELECT 5. CX3 Sample Probe Maintenance or type 5 and ENTER. The sample probe arm will rotate away from the electrolyte injection cup.
 - iv. Remove the rear shield located over the creatinine chemistry reaction cup.
- 2. Disconnect line #73 from the front of the Electrolyte Injection Cup (EIC).
- 3. Press down on and twist the EIC clockwise until it pops up (Figure 9-135).
- 4. Remove lines #19, #39, and #72 from the rear of the EIC (Figure 9-136).

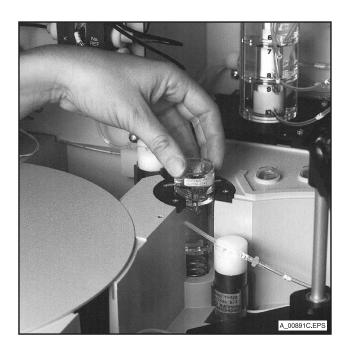
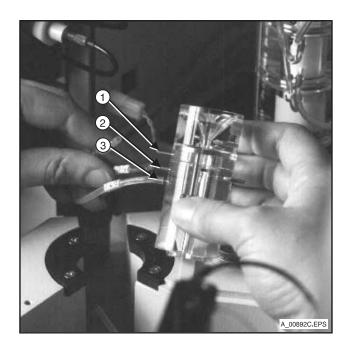


Figure 9-135. Twist EIC Clockwise



- 1 Line #19
- 2 Line #39
- 3 Line #72

Figure 9-136. Remove Lines #19, #39, and #72

5. Remove the two screws holding the EIC assembly together. Pull the separating plates out and set aside (Figure 9-137).

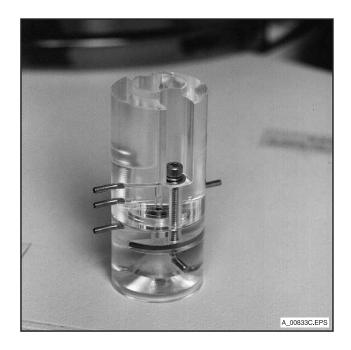
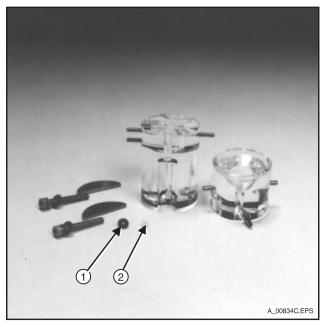


Figure 9-137. Separate the EIC

Pull apart the upper and lower sections. Remove quad-ring (Figure 9-138).

NOTE

The EIC will have an additional colored or clear spacer (washer) under the quad-ring. Take care to not dislodge the spacer. However, if dislodged, replace in lower section of the EIC before replacing quad-ring.

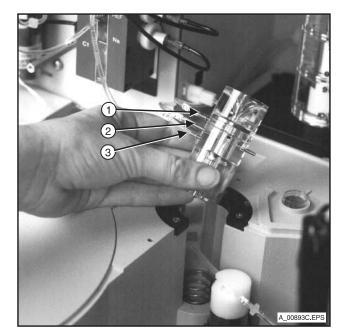


- 1 Quad-ring
- 2 Spacer

Figure 9-138. Disassembled EIC

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- 7. Press new quad-ring (P/N 946335) into the lower section of the EIC (on top of the spacer).
- 8. Reassemble the EIC in reverse of the above steps.
- Reconnect tubing to appropriate ports and place EIC back in position (Figure 9-139).
- Replace rear shield over Creatinine chemistry reaction cup. Be careful that wires and tubes are not pinched under edges of cover.
- 11. Press PREV SCREEN to home the sample probe.
- 12. Replace the front shield over BUN, glucose and calcium or total protein chemistry reaction cups. Be careful that wires and tubes are not pinched under edges of cover.
- 13. Replace and secure the four retaining nuts and three thumb screws.



- 1 Line 19
- 2 Line 39
- 3 Line 72

Figure 9-139. Reconnect EIC Tubing

9.8.7 Sample/Reagent Probe Assembly Replacement

9.8.7.1 Sample/Reagent Probe Assembly Replacement (Original Probes)

- From the MASTER Screen, press SYSTEM IDLE. The screen will prompt: "Continue with the shut down procedure (Y/N)?".
- 2. Press **Y**, then **ENTER**. The screen will display:
 - "SYSTEM IDLE" "CX3/ISE:STANDBY" "CONSOLE:" "CX4: STANDBY"
- Press F4 RESUME. The screen will prompt: "This will reboot the system. Continue with the Resume procedure (Y/N)?".
- 4. Press Y, then ENTER. The message display window will prompt: "Press PREV SCREEN to continue" (flashing message).

- 5. Press **PREV SCREEN**. A window will pop up giving four boot options.
- Press 1. A red "POWER DOWN SCREEN" will prompt you to: "Turn off CX Instrument and/or PC Console Now".
- 7. Turn the PC console power off using the switch located on the front of the console unit.
- 8. Open the right front door of the instrument (Figure 9-140). Leave the AUX power switch ON. Press the MAIN power switch to OFF. The green power lights for both MAIN and AUX will go out. Close the right front door.
- Open the cover to the electronics compartment. Refer to the Diagnostics and Troubleshooting Guide, Paragraph 4.4, for instructions on access to the electronics compartment.

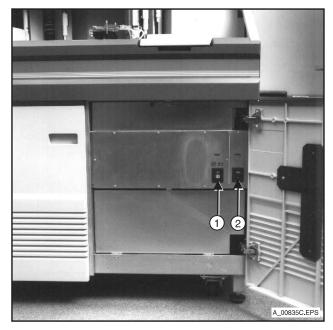
CAUTION

To prevent damage due to static electrical discharge, make certain that the wrist strap found in the central portion of the card cage is attached to the operator's arm prior to touching any boards. In order to provide adequate grounding, the wrist strap must be attached directly to the operator's bare arm. The wrist strap should not be attached to a sleeve or any other clothing on the arm.

10. Locate the level sense circuit board marked "LEV SEN 225" near the middle of the card cage (Figure 9-141).

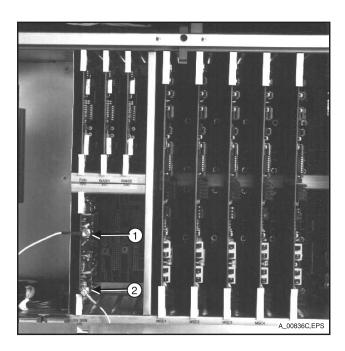
NOTE

When replacing both sample and reagent probes, it is recommended that one probe is replaced at a time. This will simplify rerouting the cables. To prevent possible damage to the probe tips it is recommended that the probes be manually lowered into the respective wash cups when working on them.



- 1 AUX Power Switch
- 2 MAIN Power Switch

Figure 9-140. Power Switch



- 1 Sample Probe Assembly P911
- 2 Reagent Probe Assembly P912

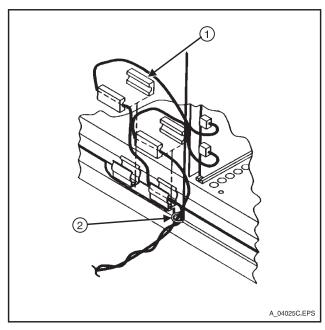
Figure 9-141. Level Sense Circuit Board

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- 11. Depending upon which probe you are installing, remove the appropriate cable from the level sense board as follows:
 - (a) Firmly press on the edge of the level sense board to prevent the board from coming out as you carefully unplug the right angle connector from the board.
 - i. To remove the Sample Probe Assembly, remove line J911, which is connected to the top of the level sense board.
 - ii. To remove the Reagent Probe Assembly, remove line J912, which is connected to the bottom of the level sense board.
- 12. Locate the appropriate split ferrite bead found in the front lower ledge of the card cage (Figure 9-142).
- 13. Push the split ferrite bead to one side to remove it from its clip.
 - (a) Separate the bead and remove the cable. Set the halves of the ferrite bead aside for later replacement.
- 14. Carefully push the metal right angle cable connector through the round rubber grommet that is used to protect the cable. If the grommet comes out of its hole in the card cage, replace by squeezing the grommet and aligning the groove in the grommet with the metal edge of the cutout in the card cage (Figure 9-142).

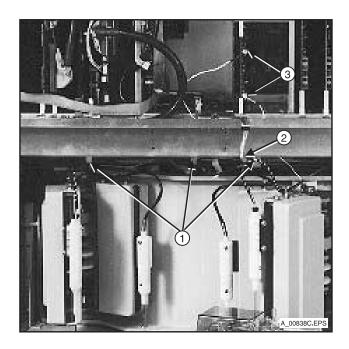
When removing screws in this area it is recommended that a lab towel be placed across any areas into which a screw or washer might be accidentally dropped.

15. Unscrew the common cable clamp located above the probe area, but underneath the card cage. Take care not to drop the Phillips screw. Remove the cable and set the screw and clamp aside for later reinstallation (Figure 9-143).



- 1 Split Ferrite Bead
- 2 Grommet

Figure 9-142. Split Ferrite Bead



- 1 Cable Clamp
- 2 Mixer Connectors
- 3 Level Sense Cables

Figure 9-143. Release Lines From Cable Clamp

 Remove the cable from any other clamps which support it under the card cage.

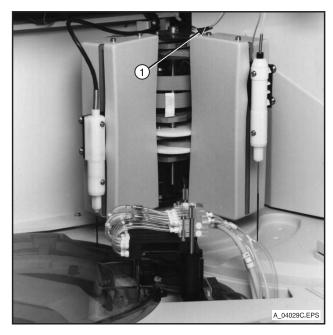
NOTE

Before going on to the next step, locate the threaded wash line as it comes out of the top of the probe that you are replacing. Use a marker to mark the portion of the line that is currently being held by the cable clamp on top of the probe crane. This will aid in later reinstallation.

- 17. Remove the thumbscrew and black cable clamp from the top of the crane hexagonal standoff. Keep the thumbscrew and the washer underneath for later reinstallation (Figure 9-144).
- 18. Locate the wash line which comes out of the top of the probe. Mark the wash line where the black plastic wrap ends. This will help when rewrapping the new probe cable and wash line. Unscrew the fitting and remove the line from the top of the probe.
- Carefully remove the plastic spiral wrap from around the level sense and wash line. Set the wrap aside for later reinstallation.
- Remove the two Phillips head screws that attach the probe assembly to the black crane support. Set both of the screws aside for later reinstallation (Figure 9-145).
- 21. The probe assembly should now be free to remove from the system.

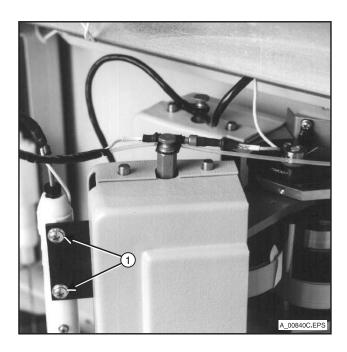
NOTE

In the following step, the probe should be installed so that the Phillips head screws are facing away from the center of the crane assembly. Install the Phillips screws securely, but do not tighten them. It will be necessary to adjust the position of the assembly on the mounting bracket. Alignment of the probe follows.



1 - Cable Clamp

Figure 9-144. Remove Cable Clamp

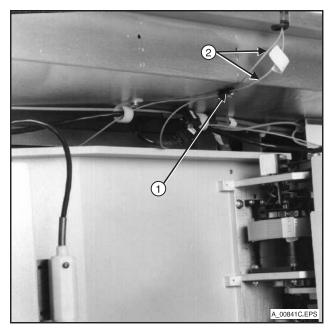


1 - Phillips Head Screws

Figure 9-145. Remove Probe from Crane Support

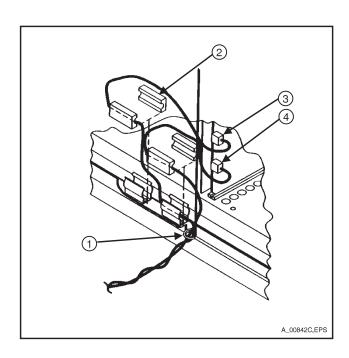
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- 22. Mount the new probe assembly to the black crane support using the two Phillips head screws which were removed in step 20.
- 23. Attach the wash line fitting to the top of the new probe.
- 24. Rewrap the spiral wrap around the wash line and the level sense cable.
- 25. Thread the cable and wash line through the clamps on the underside of the card cage.
- 26. Using the Phillips head screw removed earlier, re-attach the common cable clamp to the underside of the card cage, with both the sample level sense cable and the reagent level sense cable in place (Figure 9-146).
- 27. Attach the cable clamp to the end of the spiral wrapped wash line and cable furthest from the probe. Attach the clamp to the hexagonal standoff on top of the probe crane.
- 28. Move the tubing back and forth to make certain it is loose in the clamp.
- 29. Carefully thread the right angled connector of the level sense cable through the round rubber grommet on the underside of the card cage. The grommet may be removed from its cutout to accomplish this. Make sure that the grommet is in place in the cutout on the floor of the card cage, so that the level sense cable is not exposed to any sharp edges (Figure 9-147).
- 30. Re-install the level sense cable in the split ferrite bead and replace the bead into the clips on the front lip of the card cage as illustrated (Figure 9-147).



- 1 Cable Clamp
- 2 Level Sense Cables

Figure 9-146. Attach Level Sense Cables to the Common Cable Clamp



- 1 Round Rubber Grommet
- 2 Split Ferrite Bead
- 3 P911 Sample Probe Connector
- 4 P912 Reagent Probe Connector

Figure 9-147. Replace Rubber Grommet

- 31. Plug the right angle connector of the level sense cable into the appropriate plug on the level sense board.
 - (a) For the Sample Probe Assembly, connect the cable to the top port of the level sense board, line J911.
 - (b) For the Reagent Probe Assembly, connect the cable to the bottom of the level sense board, line J912.
- 32. Make sure that there is enough slack in the level sense cable at the probe crane so that the crane movement does not pull on the connector. There should be very little slack in the level sense cable within the card cage area.

Since the power is off, the crane may be manually moved through its complete range of motion (left/right) to ensure that the level sense cable and wash line are not restricting motion. Re-orient the cable and wash line to eliminate any restriction.

- 33. Return the wrist strap to its storage position.
- 34. Replace the metal card cage cover as described in the Diagnostics and Troubleshooting Guide, Paragraph 4.4.
- 35. Close the hinged electronic compartment cover.
- 36. Open the right front compartment door and press the MAIN Power switch to the ON position. The MAIN and AUX power switch green lights will come on. Close the door.
- 37. Turn the PC console power ON using the switch on the front of the console unit.
- 38. After initialization is complete, from the MAS-TER Screen, press the F4 SPECIAL FUNC-TION key.
- 39. From the SPECIAL FUNCTIONS Screen, move the cursor to 3. Diagnostics/Alignment and press the **SELECT** key.

NOTE

It is necessary to perform probe assembly alignment, vertical probe alignment, and height adjustment whenever the probe assembly is removed or replaced.

- 40. Press F4 CX4 DIAG. If the screen prompts "Entering CX4 Diagnostics requires 5 minutes. Do you wish to continue (Y/N)?". Press Y, then ENTER.
- 41. The probe assembly alignment procedure is accessed through the CX4 diagnostics MAIN MENU Screen.
 - (a) Press **F2 SET UP OPTIONS** to select operation mode.
 - (b) Press SELECT to enter into the EXTENDED mode.
 - (c) Press **PREV SCREEN** to return to the diagnostics MAIN MENU Screen.
 - (d) For sample probe replacement, cursor and **SELECT** 5. Sample System, or type **5** and **ENTER**. Proceed to step 42.
 - (e) For reagent probe replacement, cursor and SELECT 6. Reagent System, or type 6 and ENTER.
- 42. Cursor and **SELECT** 1. Probe, or type **1** and **ENTER**
- 43. Press F1 CONTINUE.
- 44. When the system is ready, press **F1 ROTARY MOTOR**.
- 45. Press **ENTER** to move the probe arm over the cuvette position.
- 46. Press **F1 VERTICAL POWER** to relieve power to the vertical motor.

CAUTION

Pressing the down arrow key releases power to the probe crane vertical motor and allows the operator to center the probe in the cuvette. Cuvette breakage may occur if the probe assembly is not gently lowered into the cuvette.

- 47. Center the probe between the front and rear walls of the cuvette.
- 48. Tighten the large Phillips head screws securing the probe assembly to the black crane support. Check to make certain that the probe remains centered in the cuvette.
- 49. Press **ENTER** to step through the probe positions. Verify that the probe is centered in the cuvette by repeating Steps 45 and 46.

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If alignment is not successful at this point, call your local Beckman office for assistance (North American customers call 1-800-854-3633). For international assistance, refer to Appendix A.

- Press F8 DIAG MENU to return to the diagnostics MAIN MENU Screen
- 51. Press F2 SETUP OPTIONS.
- 52. Press **SELECT** to enter into the ALIGNMENT mode.
- 53. Press **PREV SCREEN** to return to the diagnostics MAIN MENU Screen.
- 54. For Probe Vertical Alignment, cursor and **SELECT** 5. Sample System, or type **5** and **ENTER**.
- 55. Cursor and **SELECT** 3. Probe Vertical Alignment, or type **3** and **ENTER**.
- 56. When Probe Vertical Alignment is complete, press **PREV SCREEN** to return to the SAMPLE HANDLING SYSTEM menu.
- 57. For Probe Height Adjustment, cursor and SELECT 7. Probe Height Adjustment or type 7 and ENTER.
- 58. Follow the procedural steps outlined on the screen.
- 59. When probe height adjustment is complete, press F8 DIAG MENU to enter the CX4 diagnostics MAIN MENU Screen.
- Press PREV SCREEN to exit CX4 diagnostics and return to the diagnostics entry screen.
- 61. Press **MASTER SCREEN** to return to the OPERATING PROGRAM MASTER Screen.

9.8.7.2 Sample/Reagent Probe Insert Replacement (Quick Connect Probes)

NOTE

When replacing both sample and reagent probes, it is recommended to replace one probe at a time. These instructions have been written to describe the replacement of one probe. Repeat Steps 10 through 29 to replace an additional probe after completing installation of the first probe.

NOTE

DO NOT remove the two Phillips head screws that support the probe assembly to the black crane support.

- From the MASTER Screen, press the IDLE key. The screen will prompt: "Continue with the shut down procedure (Y/N)?".
- Press the Y key, then ENTER. After a short delay, the screen will display the following message in the status area:

"SYSTEM IDLE" "CX3/ISE: STANDBY" "CONSOLE: " "CX4: STANDBY"

- Press F4 RESUME. The screen will prompt: "This will reboot the system. Continue with the Resume procedure (Y/N)?".
- Press Y, then ENTER. The message display window will prompt: "Press PREV SCREEN to continue" (flashing message).
- Press PREV SCREEN. A window will pop up giving four boot options.
- Press 1. A red "POWER DOWN SCREEN" will prompt you to: "Turn off CX Instrument and/or PC Console Power Now".
- 7. Turn the PC console power off using the switch located on the front of the console unit.

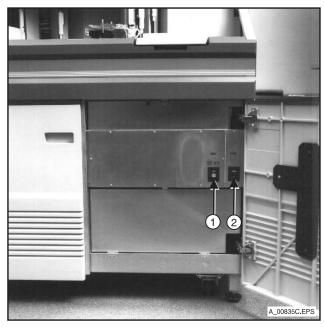
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- Open the right front door of the instrument (Figure 9-148). Leave the AUX power switch ON. Press the MAIN power switch to OFF. The green power lights for both MAIN and AUX will go OUT. Close the compartment door.
- Open the cover to the electronics compartment. Refer to the Diagnostics and Troubleshooting Guide, Paragraph 4.4, if necessary, for access instructions for the electronics compartment. Opening the cover is done only to provide more room to work on the probe.

Make sure that the auto-loader cover, sample carousel cover, and reaction carousel cover are in place before starting. It is also recommended that a lab towel be placed over any area into which a screw or small part may be dropped while performing the steps below.

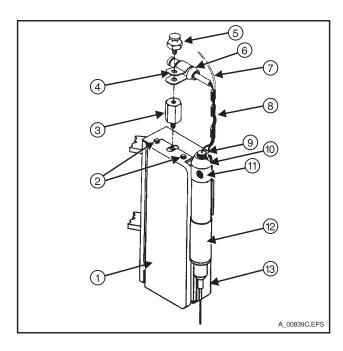
Align the probe that is being serviced over the appropriate wash cup and gently push the probe down into the cup. This will protect the probe in the following steps and catch any excess fluid that may remain in the probe and washline.

- 10. Carefully unwrap the black plastic spiral wrap from around the level sense cable and washline, starting at the probe and ending at the hexagonal standoff. (Figure 9-149A).
- 11. Unscrew the threaded washline fitted from the top of the probe.
- 12. Carefully disconnect the level sense cable connection at the black clamp located next to the hexagonal standoff by pulling against the raised collars of each half of the connector. Only the probe level cable should be threaded through the black cable clamp (Figure 9-149A). DO NOT TWIST OR PULL ON THE WIRES.



- 1 AUX Power Switch
- 2 MAIN Power Switch

Figure 9-148. Power Switch



- Α
- 1 Inner Crank Cover
- 2 Crank Cover Studs
- 3 Hexagonal Standoff
- 4 Cable Clamp
- 5 Thumb Screw
- 6 Level Sense Cable Connection
- 7 Washline

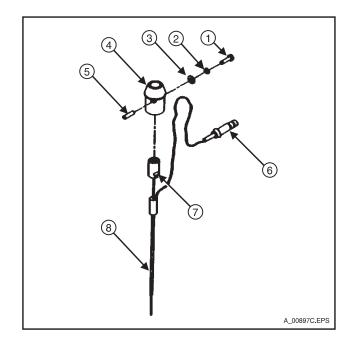
- 8 Spiral Wrap
- 9 Threaded Washline
- 10 Plastic Probe Top
- 11 Top Phillips Screw
- 12 Probe Housing
- 13 Outer Crank Cover

Figure 9-149. Sample/Reagent Probe Replacement

- 13. Remove the single, small Phillips head screw and two washers (one inner flat washer and one outer lock washer) located at the TOP of the probe housing, opposite the upper large Phillips head mounting screw (Figure 9-149B).
 - (a) DO NOT remove the bottom screw.
 - (b) Set screw and washers aside for later reinstallation.
- 14. Lift the plastic probe top (along with the internal metal probe) from the probe housing. A slight twisting motion may be necessary if the fit is tight (Figure 9-149B).

In the next step, use care in removing the small metal alignment pin. It is round and will roll easily.

- 15. Using a wooden applicator stick or similar tool (DO NOT use anything sharp), push the metal alignment pin out of the side of the plastic probe top (Figure 9-149B). This pin holds the metal internal portion of the probe in place. Set the pin aside for later reinstallation.
- 16. Remove the metal internal portion of the probe from the white plastic probe top and discard (Figure 9-149B).
- 17. Place the top of the new quick connect internal metal probe into the white plastic top of the probe holder.
- 18. Align the cutout in the top of the internal metal probe with the large opening in the side of the white plastic probe top (Figure 9-149B).
- 19. Insert the metal alignment pin into the hole to lock the internal probe in place. Use a wooden applicator stick or similar tool to press the pin firmly in place (Figure 9-149B). DO NOT use anything sharp.



В

- 1 Phillips Head Screw
- 2 Lock Washer
- 3 Flat Washer
- 4 Probe Top
- 5 Alignment Pin
- 6 Cable Clamp Goes Here
- 7 Cutout in Internal Probe Aligns With Large Opening in Probe Top
- 8 Internal Metal Probe

Figure 9-149. Sample/Reagent Probe Replacement

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- 20. Lay the new level sense cable into the groove on the outside of the white plastic probe top.
 - (a) The fit between the groove and the cable is very tight. Press the cable firmly to ensure that it is properly seated in the groove.

In the following step, use care in inserting the new probe to prevent possible damage to the teflon coating of the metal probe tip.

- 21. Remove any protective covering from the new probe. (Figure 9-149B).
 - (a) Align the small screw hole in the white plastic probe top with the screw hole in the probe housing (which is still attached to the crane arm).
 - (b) Insert the new probe and white plastic probe top assembly into the probe housing which is still attached to the crane arm.
- 22. Replace the small, single Phillips head screw and both the inner flat washer and outer lock washer. It may be necessary to rotate the probe top slightly to align the screw holes (Figure 9-149B).
 - (a) Firmly plug the new probe connector into the connector on the existing level sense cable (which runs into the card cage on the system).
- 23. Firmly screw in the washline fitting in the top of the probe assembly (Figure 9-149A).

NOTE

To perform the next step it may be necessary to move the part number tag found on the level sense line of the probe as far away from the probe as possible. If necessary, the tag may be removed.

- 24. Rewrap the black plastic spiral wrap around the washline and the level sense cable.
- 25. Make sure the washline tubing is outside the new cable clamp.
- 26. Check to make sure that there is enough slack in the level sense cable at the probe crane to allow the crane to move without pulling on the connector.

NOTE

At this point in the procedure, the main power is off. The crane should be manually raised up to the top of its travel. The crane should then be moved through its complete range of movement (Left/Right) to ensure that the level sense cable and washline are not restricting crane motion. If crane motion is restricted, the cable and washline must be re-oriented to eliminate the restriction. In addition, the probe should also be carefully moved up and down in the appropriate wash cup to check for restriction.

- 27. If a second probe is to be changed at this time, repeat steps 10 through 26.
- 28. Close the hinged electronics compartment cover (refer to paragraph 4.4 of the Diagnostics and Troubleshooting Guide for detailed instructions, if necessary).
- 29. Open the right front compartment door and press the MAIN power switch to the ON position. The MAIN and AUX power switch green lights will come on. Close the compartment door.
- 30. Turn the PC console power ON using the switch on the front of the console unit.

NOTE

Probe assembly alignment, vertical probe alignment, and height adjustment is necessary whenever the assembly is removed or replace.

- 31. After initialization is complete, from the MASTER Screen, press the **F4 SPECIAL FUNCTION** key.
- 32. From the SPECIAL FUNCTIONS Screen, move the cursor to **3**. Diagnostics/Alignment and press the **SELECT** key.
- 33. Press **F4 CX4 DIAG**. If the screen prompts "Entering CX4 Diagnostics requires 5 minutes. Do you wish to continue (Y/N)?". Press **Y**, then **ENTER**.
- 34. The probe assembly alignment procedure is accessed through the CX4 diagnostics MAIN MENU Screen.
 - (a) Press **F2 SET UP OPTIONS** to select operation mode.

- (b) Press SELECT to enter into the EXTENDED mode.
- (c) Press **PREV SCREEN** to return to the diagnostics MAIN MENU Screen.
- (d) For sample probe replacement, cursor and SELECT 5. Sample System, or type 5 and ENTER. Proceed to step 35
- (e) For reagent probe replacement, cursor and SELECT 6. Reagent System, or type 6 and ENTER.
- 35. Cursor and **SELECT** 1. Probe, or type **1** and **ENTER**.
- 36. Press F1 CONTINUE.
- 37. When the system is ready, press **F1 ROTARY MOTOR**.
- 38. Press **ENTER** to move the probe arm over the cuvette position.
- 39. Press **F1 VERTICAL POWER** to relieve power to the vertical motor.

CAUTION

Pressing the down arrow key releases power to the probe crane vertical motor and allows the operator to center the probe in the cuvette. Cuvette breakage may occur if the probe assembly is not gently lowered into the cuvette.

- 40. Center the probe between the front and rear walls of the cuvette.
- 41. Tighten the large Phillips head screws securing the probe assembly to the black crane support. Check to make certain that the probe remains centered in the cuvette.
- 42. Press **ENTER** to step through the probe positions. Verify that the probe is centered in the cuvette by repeating Steps 38 and 39.

NOTE

If alignment is not successful at this point, call your local Beckman office for assistance (North American customers call 1-800-854-3633). For international assistance, refer to Appendix A.

- 43. Press **F8 DIAG MENU** to return to the diagnostics MAIN MENU Screen.
- 44. Press F2 SETUP OPTIONS.

- 45. Press **SELECT** to enter into the ALIGNMENT mode.
- 46. Press **PREV SCREEN** to return to the diagnostics MAIN MENU Screen.
- 47. For Probe Vertical Alignment, cursor and **SELECT** 5. Sample System, or type **5** and **ENTER**.
- 48. Cursor and **SELECT** 3. Probe Vertical Alignment, or type **3** and **ENTER**.
- When Probe Vertical Alignment is complete, press PREV SCREEN to return to the SAMPLE HANDLING SYSTEM menu.
- For Probe Height Adjustment, cursor and SELECT 7. Probe Height Adjustment or type 7 and ENTER.
- 51. Follow the procedural steps outlined on the screen.
- 52. When probe height adjustment is complete, press **F8 DIAG MENU** to enter the CX4 diagnostics MAIN MENU Screen.
- 53. Press **PREV SCREEN** to exit CX4 diagnostics and return to the diagnostics entry screen.
- 54. Press **MASTER SCREEN** to return to the OPERATING PROGRAM MASTER Screen.

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9.8.8 Cleaning C CAM Vent Line #124 (CX7 users only)

If line #124 of the CX3 C Cam should show evidence of Creatinine reagent or crystals it should be cleaned as follows:

 Lower peri-pump cover and remove protective cover to expose the C Cam pinch valve (Figure 9-150 or 9-151).

NOTE

There are two different models of pressure bars on the pinch valve assembly. The two different models are represented in Figures 9-150 and 9-151. Please refer to the figure which represents the type of pressure bar on your instrument.

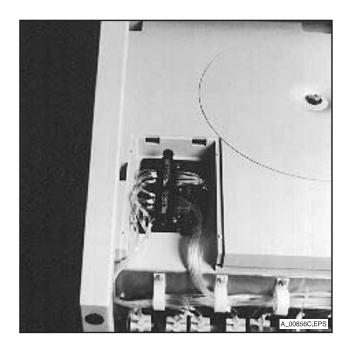
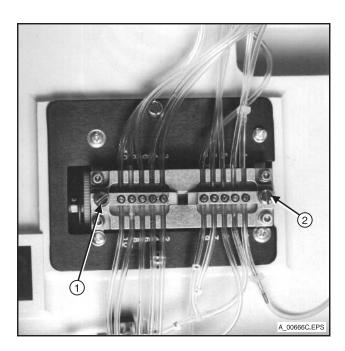


Figure 9-150. C Cam Pinch Valve



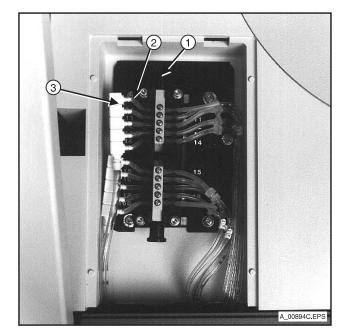
- 1 Controls Inlet Tube Lines
- 2 Controls Outlet Tube Lines

Figure 9-151. Pinch Valve

- Release upper pressure bar by pulling up on the black knob. If your system has the other model type pinch valve assembly, loosen the screws that hold down the pressure bar. Gently lift the bar upward (Figure 9-152).
- 3. Disconnect line #124 from the white tubing manifold.
- 4. Rinse tubing with deionized water to remove any residue. Also at this time use a moistened lintless tissue to clean up any reagent that may have leaked onto the pinch valve assembly.
- Open pressure bar and reconnect line #124 to the white tubing manifold then insert it into its proper position on the pinch valve.
- 6. Close pressure bar.
- Replace sliding cover over pinch valve "C" assembly. Close peri-pump cover. Be careful not to pinch the tubing.

9.8.9 CX3 Lamp Test

For the CX3 Lamp Test, refer to the CX4/CX5/CX7 DELTA Diagnostics and Trouble-shooting Guide, Section 4.2.3.



- 1 Pressure Bar Knob
- 2 Line #124
- 3 Tubing Manifold

Figure 9-152. Release Pressure Bar

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9.8.10 Clean All Exposed Working Surfaces

- Remove wash station cover by pulling up on the locking pins (one on each side) and pulling the cover straight up and off (Refer to Figure 9-2).
- 2. Remove autoloader cover by lifting straight up and off (Figure 9-153).
- 3. Remove sample carousel cover by lifting straight up and off (Figure 9-153)
- 4. Remove reaction carousel cover as follows (Figure 9-153):
 - (a) Carefully rotate the cover counterclockwise while lifting slightly to free the cover alignment tabs from the grooves in the tub. Be careful not to bend any probes or mixers by lifting too high or forcing the cover.
 - (b) Once the cover clears the mixer and probes, lift up and towards the front of the instrument.
- Clean all covers and sectors with disinfectant soap and deionized water.
- Wipe all exposed surfaces on the system (including keyboard, table surfaces and sides of console) with 70% isopropanol or a 10% bleach solution.
- 7. Replace the reaction carousel cover first, aligning tabs in grooves, being careful not to bend the probes. Replace sample turntable cover, autoloader cover, and wash station cover in their positions.
- 8. CX7 users: clean the CX3 reagent compartment door and covers around chemistry reaction cups with a clean, slightly moistened lintless cloth, then wipe dry with lintless tissue.
- 9. Press SYS HOME.



- 1 Autoloader Cover
- 2 Sample Carousel Cover
- 3 Reaction Carousel Cover

Figure 9-153. Module Covers

9.8.11 Clean Reagent Compartment Shelf (CX7 Users Only)

- Open CX3 reagent compartment door.
- Clean reagent compartment shelf with lintless cloth slightly moistened with 70% isopropanol or 10% bleach solution.
- 3. Close reagent compartment door.

CX3:

9.8.12 Enzymatic Flow Cell Cleaning (CX7 Users Only)

The following Enzymatic Flow Cell Cleaning procedure should be performed whenever a yellow discoloration at or above the $\rm CO_2$ Acid port is visible. (Chloride electrode maintenance must be performed every time the Enzymatic Cleaning of the Flow Cell Procedure is performed; refer to 9.5.5).

- Open CX3 reagent compartment door.
- 2. Remove the tubing from the CX3 wash solution container and place it into a bottle containing 70% isopropanol.
- 3. Prime as follows:
 - (a) From the MASTER Screen, press F4 SPECIAL FUNCTION.
 - (b) Cursor and SELECT 1. Prime or type 1 and ENTER.
 - (c) Cursor and **SELECT** Wash Solution and Ratio Pump.
 - (d) Press F1 START PRIME.
 - (e) Operator is prompted to enter the number of prime cycles. Type 24 and press ENTER. The display indicates the number of primes remaining.
 - (f) Press MASTER SCREEN.

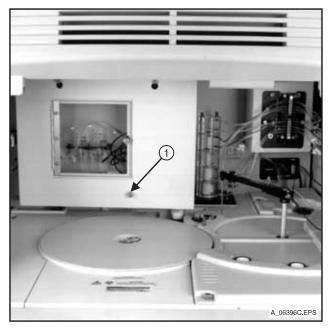
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4. Prepare Enzymatic Flow Cell Cleaning Solution as follows:

NOTE

An Enzyme Cleaning Kit (P/N 443369) is required to perform this procedure. The kit includes two Luer connectors, one 5-mL syringe, one flow cell scrub kit, and two clamps. Flow Cell Scrub Kit (P/N 443372) contains enzyme tablets only, and can be purchased separately.

- (a) Remove seal over one of the flow cell scrub enzyme tablets.
- (b) Place 5 mL of deionized water into a small beaker.
- (c) Place tablet in beaker. Let sit until tablet dissolves completely (approximately 5 minutes). The dissolved tablet should sit for no longer than 30 minutes before use.
- 5. Prepare System for Enzymatic Flow Cell Cleaning as follows:
 - (a) Prevent the system from autopriming as follows:
 - i. Press F4 SPECIAL FUNC-TIONS.
 - ii. Cursor and **SELECT** 6. Maintenance or type **6** and **ENTER**.
 - iii. Cursor and SELECT 9) CX3 Prevent Autoprime or type 9 and ENTER.
 - (b) Remove the flow cell cover as follows:
 - Loosen the captive screw at the bottom of the flow cell cover (Figure 9-154).
 - ii. Grasp the flow cell cover.
 - iii. Carefully lift up and over the two fixed guide screws.
 - iv. Set the cover aside for later reinstallation.



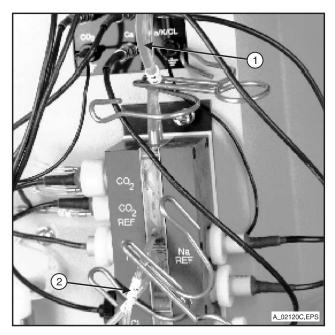
1 - Captive Screw

Figure 9-154. Removing Flow Cell Cover

- (c) Using one of the tube clamps, provided with the enzyme cleaning kit, securely clamp the TOP FRONT piece of electrolyte drain tubing (line #71) approximately one inch (25 mm) from the top of the flow cell (Figure 9-155). This will prevent the back flow of reagent into the flow cell.
- (d) Using the other clamp, clamp off the FRONT TOP CO₂ Acid tubing (line #57) on the flow cell as close to the connector as possible (Figure 9-155). This is to prevent acid inhibition of the cleaning solution.

6. Clean the Flow Cell as follows:

- (a) Disconnect the flow cell tubing (line #72) to the right of the flow cell solenoid valve (Figure 9-156).
- (b) Completely fill syringe with FLOW CELL CLEANING SOLUTION. Tap syringe gently and remove any air bubbles existing in the syringe.



- 1 Line #71, Electrolyte Drain Tubing
- 2 Line #57, CO_2 Acid Tubing

Figure 9-155. Flow Cell Lines #71 and #57 Clamped



Figure 9-156. Disconnect Flow Cell Tubing

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- (c) Place a Luer connector on the syringe and attach to line #72 leading to the flow cell solenoid valve (Figure 9-157).
- (d) When this connection is secure, remove the tubing from the flow cell solenoid valve and remove the clamp from the flow cell drain line (#71). Leave clamp attached to line #57.
- (e) Slowly inject the FLOW CELL CLEANING SOLUTION into the flow cell (Figure 9-158). Be sure that liquid is filling the flow cell and that there are no air bubbles in the line. DO NOT REMOVE SYRINGE FROM THE LINE.
- (f) Immediately replace the clamp on the TOP FRONT drain tubing (line #71) approximately one inch from the top of the flow cell.
- (g) Once the clamp is secure, replace line #72 in the flow cell solenoid valve.
- (h) Remove syringe and Luer connector and reconnect line #72.
 - i. Allow the system to stand idle for 15 minutes.
- 7. Remove clamps from CO₂ Acid line #57 and electrolyte drain tubing line #71.
- 8. Press **PREV SCREEN** to conclude this procedure. Allow system to initialize. Press **MASTER SCREEN**.



Figure 9-157. Attach Syringe to Line #72

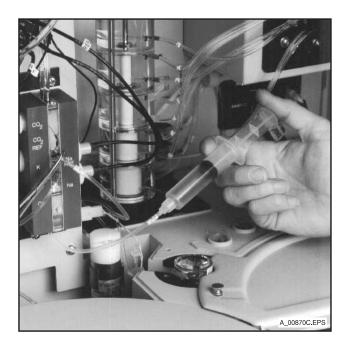


Figure 9-158. Inject Flow Cell Cleaning Solution

- Remove wash solution tubing from the 70% isopropanol bottle, wipe outside with lintless tissue and place it into the 10-liter wash solution container. (*DO NOT use the one-liter CX4 system wash concentrate container.)
- 10. Prime as follows:
 - (a) From the MASTER Screen, press **F4 SPECIAL FUNCTION**.
 - (b) Cursor and SELECT 1. Prime or type 1 and ENTER.
 - (c) Cursor and **SELECT** Wash Solution, Ratio Pump.
 - (d) Press **F1 START PRIME**.
 - (e) Operator is prompted to enter the number of prime cycles. Type 20 and press ENTER. The display indicates the number of primes remaining.
- 11. Replace the wash solution tubing into the CX3 wash solution container.
- 12. Close compartment cover.

Upon completion of the Enzymatic Flow Cell Cleaning procedure, the chloride electrode maintenance MUST be performed. Proceed to step 2 of Paragraph 9.5.5 to clean the chloride electrode.

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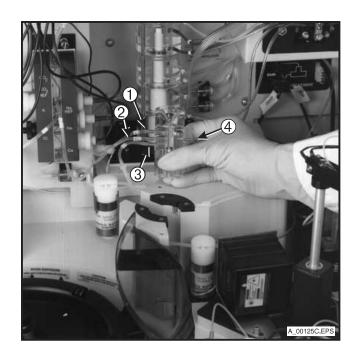
9.8.13 Flushing Electrolyte Injection Cup Ports (CX7 Users Only)

This procedure should be performed if the Electrolyte Injection Cup (EIC) overflows, or as part of troubleshooting for erratic electrolyte results.

- Remove the front shield (Figure 9-40) over the BUN, glucose and calcium or total protein chemistry reaction cups as follows:
 - (a) Unscrew and remove the three retaining nuts and one thumb screw.
 - (b) Gently lift shield off.
- From the MASTER Screen, press F4 SPECIAL FUNCTIONS. From the SPECIAL FUNCTIONS Screen, cursor and SELECT 6. Maintenance Procedures, or type 6 and press ENTER.
- From the Maintenance Procedures screen cursor and SELECT 5. CX3 Sample Probe Maintenance. This will move the sample probe out of the way.
- Remove the rear shield over the creatinine chemistry reaction cup by removing the one retaining nut and the two thumb screws.
- 5. Disconnect line #73 from the front of the Electrolyte Injection Cup (EIC).
- Remove the EIC by pushing down on the cup and rotate clockwise until it pops up. (Figure 9-136).
- 7. Remove lines #19, #39 and #72 from the rear of the EIC. (Figure 9-136).
- Remove EIC from instrument. Using a syringe filled with hot water, force the hot water through the top of the EIC while closing off three (3) of the four ports with fingers. Liquid should come out of the port not covered (Figure 9-137).
- 9. Repeat Step 8 until all ports have been cleaned.
- Reconnect the three tubing lines on the proper port positions on the rear of the EIC. (See Figure 9-160 for proper tubing orientation).



Figure 9-159. Flushing the Electrolyte Injection Cup Ports



- 1 Line #19
- 2 Line #39
- 3 Line #72
- 4 Line #73

Figure 9-160. Port Line Tubing on the EIC

- 11. Push EIC down and rotate counterclockwise to lock into place.
- 12. Reconnect tubing line #73 to the front of the EIC.
- 13. Replace rear cover and screws.
- 14. Press **PREV SCREEN** to move sample probe back into position.
- 15. Replace front cover and screws.

9.8.14 Flushing the Reaction Cup Preheater (CX7 Users Only)

This procedure should be performed when troubleshooting erratic results, low results, or reaction cup not filling.

- From the MASTER Screen, press F4 SPECIAL FUNCTIONS. From the SPECIAL FUNCTIONS Screen, cursor and SELECT 6. Maintenance Procedures, or type 6 and press ENTER.
- 2. From the Maintenance Procedures screen cursor and **SELECT** 9. CX3 Prevent Autoprime, or type **9** and then press **ENTER**.
- 3. Remove the fill line connected to the right side of the red peri pump tubing corresponding to the reaction cup.
- Fill a syringe with hot water and attach the syringe to a spare peri pump tube. Attach the other end of the spare peri pump tube to the disconnected line tubing.
- 5. Compress the syringe so that the water in the syringe goes into the reaction cup through the preheater. The cup will overflow. Sponge off the overflow from around the cup. Using a disposable pipet, draw off the remaining liquid from the top of the reaction cup.
- 6. Reconnect the line tubing to the proper peri pump tubing.
- Press PREV SCREEN to exit procedure.
- 8. Prime the chemistry cup five (5) times.

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9.8.15 Bleaching the Reagent Pickup Straw and Reagent Cup (CX7 Users Only)

This procedure is recommended for troubleshooting erratic results or a chemistry that will not calibrate.

- Open the CX3 reagent compartment door.
- 2. Remove the reagent cap and attached straw from the reagent bottle and place in a beaker with a 10% bleach solution.
- 3. Prime the reagent as follows:
 - (a) From the MASTER Screen, press F4 SPECIAL FUNC-TIONS. From the SPECIAL FUNCTIONS Screen, cursor and SELECT 1. Prime, or type 1 and press ENTER.
 - (b) Cursor and SELECT the reagent to be primed and press F1 START PRIME and press ENTER.
 - (c) Type **10** and press **ENTER** for the number of CX3 prime cycles.
- 4. When the prime cycles are completed, remove the 10% bleach solution and place the reagent straw into a beaker filled with deionized water. Repeat Step 3.
- Replace reagent cap and straw into the appropriate reagent bottle after the prime cycles are completed. Repeat Step 3.
- Adjust the reagent volume if necessarv.
- 7. Calibrate the reagent when prime cycles are completed.

9.8.16 Removal of Bubbles from Ratio Pump (CX7 Users Only)

This procedure should be performed when troubleshooting for poor precision or poor recovery, or if large bubbles are observed in the ratio pump.

- From the MASTER Screen, press F4 SPECIAL FUNCTIONS. From the SPECIAL FUNCTIONS Screen, cursor and SELECT 1. Prime, or type 1 and press ENTER.
- Cursor and SELECT Ratio Pump and press F1 START PRIME.
- Type 1 and ENTER for the number of CX3 prime cycles.
- On the downward motion of the ratio pump, pinch the EVEN numbered line of the affected chamber with fingers.
- 5. During the upward motion of the pump, release the line.
- Repeat steps 2-5 until bubbles are no longer present.
- When complete, prime the ratio pump several times to force fluid through the lines.

9.8.17 Flushing the Flow Cell (CX7 Users Only)

This procedure should be performed when troubleshooting for drift, back-to-back and range errors that may be caused by plugs or debris lodged in the electrode ports.

- From the MASTER Screen, press F4 SPECIAL FUNCTIONS. From the SPECIAL FUNCTIONS Screen, cursor and SELECT 6. Maintenance Procedures, or type 6 and press ENTER.
- From the Maintenance procedures screen cursor and SELECT 9. CX3 Prevent Autoprime, or type 9 and then press ENTER.
- Use a tube clamp or hemostat to block off line #71 at the top of the flow cell. Line the area under the flow cell with an absorbent wipe.

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- Remove line #72 at the bottom of the flow cell. Using a syringe with a small piece of extra tygon tubing attached, connect the open end of the tubing to the flow cell.
- Without removing the tube clamp or hemostat, remove line #71 from the flow cell. Remove line #57 from the front of the flow cell in order to allow residual acid to leak out.
- Draw back on the syringe. This will withdraw any remaining solution left in the flow cell and remove any material that may be causing the occlusion of the small lumen.

The procedure may be concluded here if the problem has been resolved. Go to Step 9. If not, continue.

- 7. Re-attach line #57. Remove the syringe and empty the contents. Fill the syringe with Electrolyte buffer.
- 8. Re-attach the syringe to the top of the flow cell in place of line #71 and flush through.
- Reassemble the lines to the flow cell and remove the tube clamp or hemostat. Prime the system as follows:
 - (a) Press PREV SCREEN two (2) times to return to the SPECIAL FUNCTIONS Screen. From the SPECIAL FUNCTIONS Screen (F4), cursor and SELECT 1. PRIME and press ENTER, or type 1 and press ENTER.
 - (b) Cursor and **SELECT** Electrolyte Reference Flow Cell and press **F1 START PRIME**.
 - (c) Type **10** and **ENTER** for the number of CX3 prime cycles.

9.8.18 Temperature Verification of Reaction Cup Heaters (CX7 Users Only)

This procedure should be performed when troubleshooting calibration failures and consistent low or high results.

NOTE

The equipment required for this procedure is a calibrated mercury or digital thermometer (accuracy of $\pm 0.1^{\circ}$ C) and a beaker filled with warm water.

- Warm the thermometer in the beaker of warm water to approximately 37°C.
 For each of the four cup chemistry modules, perform the following:
 - (a) Prime the module as follows:
 - From the MASTER Screen, press F4 SPECIAL FUNC-TIONS.
 - ii. Cursor and SELECT 1. PRIME or type 1 and ENTER.
 - iii. Cursor and SELECT the chemistry (BUN3, CRE3, GLU3, CA3 or TP3). Press F1 START PRIME.
 - iv. Type **3** for number of primes and press **ENTER**.
 - (b) After priming is concluded, manually turn the "FILL" peri-pump for the selected chemistry counterclockwise one complete revolution.
- 2. Measure the temperature inside the reaction cup thirty (30) seconds after turning the "FILL" peri-pump.
 - (a) Carefully lower the thermometer into the center of the reaction cup without disturbing the magnetic stirrer or touching the electrode (approximately, but not more than two inches).
 - (b) Allow the temperature reading to stabilize.

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(c) The temperature reading should be 37°C ±1°C for BUN3, GLU3, CA3 or TP3. CRE3 should be 41°C ±1°C.

If the temperature of the reaction cup is out of the specified range, contact Clinical Support Center (Hotline) at 1-800-854-3633.

9.8.19 Creatinine Cup and Stirrer Cleaning Procedure Using CX3 CO₂ Acid

This procedure is recommended if a white build-up on the stirrer or in the cup is observed. This procedure is to be used in addition to the regular two week maintenance cleaning procedure for troubleshooting creatinine chemistry problems.

NOTE

When removing the stirrer, unscrew retainer nut and partially withdraw photo-detector assembly from reaction cup. Remember to screw the retainer nut back in when performing any other part of the maintenance procedure.

- 1. Prepare a fresh 1:5 dilution of CX3 CO₂ Acid Reagent (P/N; 443330) as follows:
 - (a) Add 2 ml of CO₂ Acid reagent to 8 ml of H₂O in a test tube or beaker and mix.
- 2. Prepare reaction cup for maintenance. Program system as follows:
 - (a) From the Master Screen, press F4 SPE-CIAL FUNCTION.
 - (b) Cursor and **SELECT**> 6. Maintenance Procedures or type 6 and **SENTER**>.
 - (c) Cursor and **SELECT>** 6. Chemistry Maintenance or type 6 and **SENTER>**.
 - (d) Cursor and **<SELECT>** CREA.
- Using a disposable transfer pipet, fill the creatinine reaction cup with the diluted CO₂ Acid reagent to a level approximately 1/4 inch (6 mm) above the sip hole.
- Allow the creatinine cup to stand for a minimum of ten (10) minutes.
- Using a disposable transfer pipet, remove the diluted CO₂ Acid reagent from the creatinine reaction cup.
- Using a disposable transfer pipet, rinse the creatinine reaction cup two times with deionized water.

NOTE

If replacing the new style sample syringe assembly (syringe plunger rod with attached tips) (P/N's 448947 or 448945) or the new style reagent syringe assembly (syringe plunger rod with attached tips) (P/N's 448976 or 448974), please refer to Section 9.6 under "Three-Month Maintenance Procedures".

The sample and reagent syringe tips should be replaced twice per month, after every 7500 assays, or if signs of wear are noticed, whichever comes first.

Replace as follows:

- 1. Remove syringe cover. (Refer to Paragraph 9.1.5.)
- 2. Fully extend the plungers to the bottom of the syringe barrels as follows:
 - (a) From the MASTER Screen, press **F4 SPECIAL FUNCTION**.
 - (b) Cursor and **SELECT** 6. Maintenance Procedures or type 6 and **ENTER**.
 - (c) Cursor and **SELECT** 3) CX4 Syringe Tip Replacement or type **3** and **ENTER**.
- 3. Turn the barrel of the reagent (right) syringe clockwise to release syringe (Figure 9-161). Loosen the round coupling nut at the base of the plunger rod of the syringe (Figure 9-162).

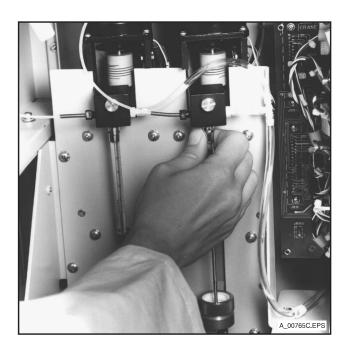


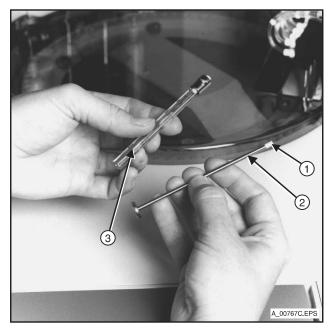
Figure 9-161. Release Syringe



Figure 9-162. Coupling Nut

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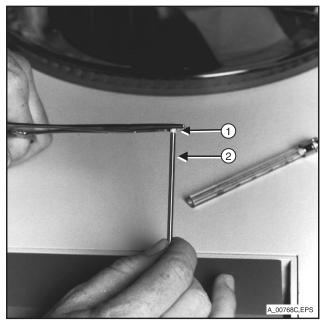
4. Remove the syringe and separate the plunger from the barrel (Figure 9-163).



- 1 Syringe Plunger Tip
- 2 Plunger
- 3 Barrel

Figure 9-163. Separate Plunger from Barrel

5. With care and not much force, grasp the syringe plunger tip using hemostats and pull to remove it from the plunger (Figure 9-164). To simplify tip removal, a small vertical incision may be made from the bottom rib to the base of the tip.



- 1 Syringe Tip 2 Plunger

Figure 9-164. Removing Plunger Tip

248408-G November 1995 9-165 6. Install a new tip on the plunger as follows:

Sample Tip P/N 444588

Reagent Tip P/N 444591

Reagent O-Ring P/N 928761

- (a) Place the tip on a benchtop or other smooth surface or in the Syringe Tip Insertion Tool (P/N 757656), with the open end face up.
- (b) Push the plunger firmly down into the plunger tip. Be sure that the plunger is completely seated in the tip and that the tip is located squarely (not tipped) on the plunger.
- Pre-wet the syringe with deionized water to limit the amount of air bubbles. Replace the plunger into the syringe barrel.
- 8. Reinstall the syringe as follows:
 - (a) Insert the base of the plunger into the white, rubber coupling.
 - (b) Re-tighten the round coupling nut finger-tight.
 - (c) Carefully pull the syringe barrel upward until the syringe Luer-lock fitting is engaged.
 - (d) Turn the syringe barrel counterclockwise to lock in place.
- 9. Repeat for the sample syringe.
- 10. Press **PREV SCREEN** to drive each of the plungers to the top of the syringes.

NOTE

If a motion error on the syringe occurs, the plunger is not properly seated in the white coupling. Repeat if necessary.

- 11. If bubbles are present in either syringe, prime as follows:
 - (a) From the MASTER Screen, press **F4 SPECIAL FUNCTION**.
 - (b) Cursor and SELECT 1. Prime or type 1 and ENTER.
 - (c) Cursor and **SELECT** Internal Probe Wash.
 - (d) Press F1 START PRIME.
 - (e) Repeat steps c and d ten times.

- 12. If bubbles persist after priming:
 - (a) Remove syringe and fill half full with deionized water.
 - (b) Tap syringe to release bubbles.
 - (c) Reinstall syringe as described in Step 8.
 - (d) Prime Internal Probe Wash as described in Step 11.
- Press MASTER SCREEN to conclude this procedure.
- 14. Replace syringe cover.

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Section 11 OPERATING PRECAUTIONS AND HAZARDS

This section lists the precautions and hazards associated with the SYNCHRON CX4 and CX7 Systems. Please read this information prior to operating the system.

11.1 CAUTIONS

11.1.1 CX4 and CX7

- 1. CX4/CX7 System operating and performance characteristics and the instructions contained in this manual are based on the system hardware configuration specified by Beckman. Beckman disclaims all liability, including all warranties, whether expressed or implied, for CX4/CX7 System performance when operated with other than the specified hardware configuration.
- 2. Use only factory-approved parts, reagents, wash solution and procedures to service the system.
- 3. If a diskette appears damaged, do not insert it into the disk drive. A scored diskette may damage a disk drive and subsequently all other diskettes placed into that drive. A scored diskette may also indicate a dirty or damaged disk drive. Call your local Beckman office for assistance (Refer to Appendix A, Sales and Service Offices).
- 4. There are no user-serviceable parts in the hydropneumatic drawer module other than those stated in Section Four of this manual and in Section Four of the Diagnostics and Troubleshooting Guide, (P/N 015-248547).
- 5. Proper performance of the system requires maintenance as directed in this manual.
- 6. When performing maintenance, service, or troubleshooting on elements of the system that have contacted sera or other biological fluids, be aware of possible pathogen contamination. Do not handle sample or solutions without proper protection. Observe standard laboratory precautions. It is always necessary to wash your hands thoroughly after performing any routine maintenance.

- 7. When performing maintenance, wear safety glasses to protect your eyes.
- 8. The reagents and other chemical preparations used with the system will not normally cause adverse reactions; however, those persons with sensitive skin should wear protective rubber gloves before attempting to work with reagents and other chemical preparations.
- 9. When blood collection tubes which contain physical barriers are used, extra care should be exercised to ensure that the barrier is tightly packed. Loose particles from the barrier could coat or plug the sample probe, flow cell, electrolyte injection cup, or cuvette washer.
- Samples should be free of all visible fibrin. Clots could coat or plug the sample probe, flow cell, electrolyte injection cup, or cuvette washer leading to instrument malfunction and/or short sampling.
- 11. Calibrators necessary for specific chemistries are described in Section Six of this manual. Be sure that the specified calibrator is in place for each calibration requested.
- 12. Calibrate with fresh calibrators after any of the following conditions:
 - -Any maintenance or repair.
 - -Any board or module adjustment.
 - —Calibration set point modification or slope, offset adjustment.
 - —System reset or restart (CX3 only).
 - -CX3 Reagent loading.
 - —Loading a calibrator diskette
- 13. To ensure optimum performance of the system, operate the system with reagent doors and all shields and covers in place.
- 14. If maintenance, adjustments, or repairs are required to correct a system malfunction, review patient results that were generated prior to this action.

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- 15. Beckman Instruments recommends that at least two levels of control materials, normal and abnormal, should be analyzed daily. Do not use controls containing diethylamine HCL, if CALC(ISE) is on the system. In addition, these controls should be run with each new calibration, with each new lot of reagent, and after specific maintenance or troubleshooting as detailed in the manuals. More frequent use of controls, or the use of additional controls, is left to the discretion of the user based on work load and work flow. However, the user should determine their own frequency based on the NCCLS Proposed Guideline C24-P INTERNAL QUAL-ITY CONTROL TESTING: PRINCIPLES AND DEFINITIONS. This document recommends that "the user should define the period of time or series of measurements within which validation of the measurement process is important, based on sample stability, reporting intervals of patient results, cost of reanalysis, work flow patterns, operator characteristics, or similar non-analytical considerations which are in addition to the expected stability of the accuracy and precision of the measuring system."
- 16. While the Maintenance Screen is active, the hydropneumatic system may automatically start during CX3 autoprime.
- 17. If triglyceride, cholesterol, HDL cholesterol or any other lipase or cholesterol esterase containing reagent are configured on the same instrument with Lipase reagent, perform the SYNCHRON Lipase Wash procedure before running each batch of Lipase tests. This procedure is described in the Limitation section of Lipase Chemistry Information Sheet in the Chemistry Information Manual.

11.1.2 CX3 Module (CX7 Users Only)

- After placing fresh CX3 wash solution on the system, perform a reagent load, then proceed to the following steps:
 - (a) Prime BUN3, GLU3, and ratio pump five times.
 - (b) Recalibrate sodium, potassium, chloride, CO₂, CALC (ISE), GLU3 and BUN3 before resuming normal operation.
- After analysis of ten consecutive urine electrolytes, one replicate of the SYNCHRON CX Calibrator Level 3 standard should be run in the serum mode for electrolytes. This will eliminate the potential for chloride drift due to matrix effects of urine samples.

- Reaction cup modules must always be reinstalled into the same positions as originally installed. These positions were carefully selected to provide a maximum in programming flexibility while maintaining a minimum interference due to reagent carryover.
- 4. Failure to operate the system with sufficient electrolyte reagent will result in erroneous results for all CX3 chemistries. In some cases, results will be obtained without reagents. Therefore, before starting any run, verify that sufficient reagent is available to complete the run.
- 5. Reagent bottles should not be handled during a sample measurement period.
- Repetitive refrigeration of the SYNCHRON CX aqueous calibrators may facilitate crystal formation. Once removed from refrigeration storage, these calibrators should remain at room temperature. The calibrator once opened is stable for thirty (30) days, or the stated expiration date on the bottle label, whichever comes first.
- When placing the chemistry cup shields back into position, be sure to properly reinstall the three thumbscrews and four retaining nuts before resuming normal operation of the system.
- 8. The Alkaline Buffer Reagent is stable for one month on the system. However, if a color change from pink to a lighter shade of pink should occur, replace with a fresh bottle of alkaline buffer reagent and refer to Paragraph 9.4.7 of Section Nine (Preventive Maintenance) for reagent load instructions.
- When reinstalling any of the CX3 chemistry modules (BUN, glucose, creatinine, total protein or calcium), be sure to properly align module to the sample probe. This will prevent damage from occurring to the sample probe.
- 10. Do not use controls containing diethylamine HCL, if CALC (ISE) is on the system.
- 11. Changes in ambient temperature and environmental conditions may result in an "excessive reference drift" message and the electrolyte chemistries must be recalibrated.
- 12. If available, the compartment light should be off during sample analysis due to possible heat generation.

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11.1.3 Minimum Volume Requirements

1. Microtubes

- (a) Fits in 13 x 100mm sector only.
- (b) Bar code labels should be placed on Microtubes the same way that labels are placed on primary sample tubes. Refer to Appendix I, Step 1(b).
- (c) Minimum volume requirements:

80 μL
140 μL
240 μL
110 μL
190 μL
60 μL dead volume + test volume

2. Sample Cups

- (a) Available sizes are 0.5 mL and 2.0 mL.
- (b) Minimum volume requirements:

	0.5 mL	2.0 mL
TP3 or CA3, BUN3 or CRE3 (1 only)	80 μL	150 μL
GLU3	110 μL	150 μL
TP3 (CSF)	160 μL	160 μL
GLU3, CL, TP3 (all CSF)	-	250 μL
Electrolytes (any/all)	110 μL	275 μL
All CX3 chems	210 μL	300 μL
CX4 tests	40 μL dead volume + test volume	175 μL dead volume + test volume

Calibration	Cup Size	Minimum Amount of Each Level of Calibrator Required
SYNCHRON CX Calibrators	2.0 mL	1060 mL
SYNCHRON CX Protein Calibrators	0.5	110 mL

11.2 HAZARDS

11.2.1 CX4 and CX7

WARNING

Do not under any circumstances operate the system until an electrical ground is provided and the power cord is properly connected to the ground.

- Disconnect the power cord when performing service procedures such as replacing circuit boards or mechanical components. Always use the antistatic wrist strap located in the electronic board compartment when removing or installing any circuit board.
- The three-pronged power cord must be connected only to a matching three-wire grounded outlet. DO NOT use an adapter to connect the power plug to a two-pronged outlet.
- Replacement or servicing of any components where contact with bare, live hazardous parts could occur, possibly resulting in electrical shock, should only be performed by qualified service personnel.
- 4. Do not use in the presence of flammable materials possible explosion hazard.
- 5. Do not place hands near any moving parts while the system is operating.
- 6. Observe all laboratory policies or procedures which pertain to handling of infectious and pathogenic materials.
- 7. System operation should be consistent with power requirements as stated in Paragraph 2.3 of this manual.
- 8. Do not tamper with or remove housing of sample bar code reader. The sample bar code reader is a Class II moving beam laser scanner. When the instrument status on the console displays the message "Running", "Homing", or "Diagnostics", the laser may be on. At all other times, the laser is off.

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11.3 CAUTION/ WARNING LABELS AND SYMBOLS

The following cautionary/warning labels appear in the indicated places on the SYNCHRON CX:

Protective Conductor Terminal



Printer



Video Display Terminal



Main Power On



Main Power Off



Printer/Terminal Power On



Printer/Terminal Power Off



Signal Input



Sample Bar Code Reader

CAUTION LASER LIGHT ACCESSIBLE WHEN COVER IS OPEN OR REMOVED DO NOT STARE INTO BEAM 270-456357-A

Sample Bar Code Reader



Sample Bar Code Reader



Carousel Covers (3)



A_00566C.EPS

Carousel Covers (3)



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11.4 WARNINGS

WARNING MANUAL CUP ASSIGNMENTS

Prior to loading sectors for use in the bar code mode of operation or programming additional manual cup assignments for a specific sector, ALL manual cup assignments must be reviewed. Failure to clear lingering manual cup assignments could result in test results matched with inappropriate patient IDs and demographics.

WARNING CALIBRATOR AND CONTROL SAMPLE **BARCODE IDs**

When creating calibrator, calibration verification or control bar code IDs. use a format that distinctly differs from that used for sample IDs. This will prevent the reporting of erroneous results due to calibrators or controls being run as patient samples, or patient samples being run as calibrators or controls.

For example Calibrator Bar code ID : CXMULTI

> Sample ID : 000001

WARNING SPECIAL CALCULATIONS

The CX4/CX7 calculates and reports the pre-programmed calculations in default units (refer to Table 6-12 in the Operating Instructions), regardless of the units selected by the operator in System Setup. The only exceptions are UREA/CREA, UREA3/ CREA3, or UREA/ CR-T which use operator-selected units.

To report calculated values which reflect units other than default units, the operator must create and enable a **Custom Calculation. The system applies** conversion factors to the custom calculations to account for differences between default units and alternative operator-selected units.

WARNING

TIMED URINE as a sample type for Reference Ranges (normal and/or critical) is not completely functional at this time. Therefore, it is recommended that TIMED URINE not be used to establish reference ranges. Operators should be aware that if TIMED URINE is the designated sample type for a given reference range, that the range will be applied to the aliquot result rather than the calculated result, and that no flags will be generated. In addition, critical reference ranges are not applied to samples with a sample type of RANDOM URINE.

WARNING QC DEFINE/REVIEW

If QC Define/Review is accessed while a control is being run on the system, the control results may not be included in the cumulative statistics. To ensure accurate cumulative statistics, it is recommended that QC Define/Review be accessed when the system is in Standby, or when controls are not being

WARNING **SECTORS**

Only amber colored SYNCHRON sectors labeled CENTRIFUGE can be centrifuged. Previous models SYNCHRON sectors will not withstand the force of centrifugation and may be damaged if centrifuged.

WARNING

The CX7/CX4 Patient Multiple Sample Report is not recommended as a patient chartable report, as a reference for verbal reports, or for transcription to written reports which would appear on patient charts. This report format does not contain sample limit flags, or instrument codes.

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WARNING

Creatinine clearance calculations using serum creatinine values downloaded from the host in other than default units (mg/dL), will result in erroneous answers. Serum creatinine values must be received from the host in default units (mg/dL) for creatinine clearance calculations to be performed correctly.

WARNING

Do not program tests requiring pretreated samples, (i.e., IgG, IgA, IgM, HDL, and TRF) with non pre-treated tests.

WARNING

After loading new multi-point calibration (>2 calibration points) diskette(s), all chemistries associated with those diskettes MUST be recalibrated before samples are run to avoid incorrect information being applied to the results.

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12.1 SYSTEM COMPONENTS

Beckman Part Number	Description
468200	SYNCHRON CX4 DELTA Analyzer (Includes Printer, Monitor, Keyboard, Operator's Manual Maintenance Log Book and Printer Paper)
468204	SYNCHRON CX7 DELTA Analyzer (Includes Printer, Monitor, Keyboard, Operator's Manual Maintenance Log Book and Printer Paper)
*	Table for Monitor, Keyboard and Printer (Includes CRT valet)
*	Printer Floor Stand
*	HP Keyboard
*	Printer, Okidata 50/60 Hz (220 VAC)
949445	Okidata Printheads
*	HP Monitor (240 VAC)
*	HP Computer (with Monitor)
464371	QC Diskettes
443670	Metering Diskettes
756932	Backup Diskettes
949937	Power Supply, Uninterruptible (240 VAC)
248408	Operating Instructions - English
248547	Diagnostics and Troubleshooting Guide - English
248538	Chemistry Information Manual - English
249005	Instrument Log Book - English
249748	Quick Reference Guide - English
*	Call Beckman Representative

12.2 CX4CE/CX4 DELTA SUPPLIES

Beckman Part Number	Description
758002	CX4 DELTA Maintenance Kit (excludes 0.2 micron filters)
759927	Wiper, vacuum probe (pkg of 12)
756613	Probe cleaner tubing assembly
946766	In-line filter/74 micron (qty 2) - Wash Concentrate Filter
758965	Swab, Poly (pkg of 5)

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12.2 CX4CE/CX4 DELTA SUPPLIES (Continued)

Beckman art Number	Description
448658	In-line Filter, 74 Micron (Probe Rinse Filter)
448663	DI Water Inlet Filter, 0.2 Micron (qty 2)
949091	Check Valve, dilute wash bottles or wash solution
758419	3-Way Valve Block Assembly
651412	Sample cup, 0.5 mL (bag of 1000)
652730	Sample cup, 2 mL (bag of 1000)
448774	Microtube (Qty 1000)
756776	Microtube (Qty 100)
442835	User-defined Reagent Cartridge (package of 12)
758407	Cuvette 5 x 5 x 30 mm (pkg of 10)
759427	Alignment Plate
759499	Mounting Bracket, Alignment Plate
756956	Carousel Alignment Centering Tool
756989	Carousel Alignment Depth Tool
757620	Centrifuge Sample Sector (16 x 100 mm) - 10 mL tubes
757621	Centrifuge Sample Sector (13 x 75 mm) - 5 mL or microtubes
757622	Centrifuge Sample Sector (13 x 100 mm) - 7 mL (tall) tubes
757623	Centrifuge Sample Sector (16 x 75 mm) - 7 mL (short) tubes
450755	Mirror
759473	Wash Sensor Feeler Gauge
928118	Printer Ribbon Cartridge
928286	Printer Paper (1250 Sheets)
928287	Printer Stand
456886	Sector Label #1 thru 10 - 10/sheet
456887	Sector Label #11 thru 20 - 10/sheet
456888	Sector Label #21 thru 30 - 10/sheet
456889	Sector Label #31 thru 40 - 10/sheet
456890	Sector Label #41 thru 50 - 10/sheet
456891	Sector Label #51 thru 60 - 10/sheet
456892	Delta "Vertical" Sector Label #1 thru 60
456009	Sector Label 13 x 100 mm 1 roll/type
455531	Sector Label 13 x 75 mm 1 roll/type
455532	Sector Label 16 x 100 mm 1 roll/type
455533	Sector Label 16 x 75 mm 1 roll/type
455539	Background Label
455540	Sector Label, #1 thru 10 - 10/sheet
455541	Sector Label, #11 thru 20 - 10/sheet

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12.2 CX4CE/CX4 DELTA SUPPLIES (Continued)

Beckman Part Number		Description
455542	Sector Label, #21 thru 30 - 10/sheet	
455543	Sector Label, #31 thru 40 - 10/sheet	
455544	Sector Label, #41 thru 50 - 10/sheet	
455545	Sector Label, #51 thru 60 - 10/sheet	

12.3 CX4CE/CX4 DELTA REPLACEMENT PARTS

Beckman Part Number	Description	
448945	Sample Syringe Assembly Maintenance Kit (1 Plunger)	
448946	Sample Syringe Plunger Guide	
448947	Sample Syringe Assembly, 50 μL	
448974	Reagent Syringe Assembly Maintenance Kit (1 Plunger)	
467729	Reagent Syringe Assembly, 500 μL	
445433	Coupling, bottom syringe holder	
444449	Coupling, top syringe holder	
758510	Drain Pump, pkgd	
758059	Sensor Assembly	
758250	Holder, Sample Probe Assembly	
758251	Holder, Reagent Probe, pkgd	
758252	Mixer Assembly, pkgd	
758383	Mixing Paddle, Gold-Plated	
949107	Mixer bearing	
758491	Wash Concentrate Bottle Insert Assembly	
758670	Syringe Pump Main Drive Assembly	
756701	Sector Reader Sensor Assembly	
758023	Board Assembly - Log/ADC	
756895	Board Assembly - Status	
758047	Board Assembly - Master Analog Controller	
758073	Board Assembly - System Interface	
758091	Board Assembly - Liquid Level Sense	
758161	Board Assembly - 4 Meg Dynamic RAM	
467522	Board Assembly, I/O SCSI	
758016	Board Assembly - Heater Controller Reaction Wheel	
758092	Board Assembly - Heater Controller Wash	
757416	Centronics Printer Cable	
442969	Printer Cable Parallel	
946604	Terminal Cable Assembly	
440087	Cable Assembly, null model to connect two types of interfacing (25 ft.)	

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12.3 CX4CE/CX4 DELTA REPLACEMENT PARTS (Continued)

	Description
759787	Cable, Power (220 VAC) - Printer & terminal (25 ft.)
464181	Cable, SCSI - Power cord from instrument to PC (25 ft.)
759137	Reaction Wheel Cover
756752	Autoloader Cover
756753	Sample Wheel Cover
758277	Wash Station Cover
758276	Wash Station Cover with Pins
891785	Cover Pins, Catch
891782	Cover Pins, Spreader
759403	Refrigerator Filter (Drop-in)
756961	Refrigerator Filter (Slide-in)
759070	Power Supply Filter
759020	Disk Drive Filter
757926	Sample Carousel
757927	Auto Loader
756892	Sample Crane
468346	Upper Card Cage Shield
758058	Board Assembly - Master Motion Controller
756887	Board Assembly - Sector Reader (not for Delta)
758170	Board Assembly - P/S Monitor CX4
756885	Board Assembly - P/S Monitor CX3
756890	Board Assembly - Z8001 CPU
756835	Board Assembly - SCSI Interface, pkgd
756886	Board Assembly - Motion Drive 1
756884	Board Assembly - Power Status
756790	Cable Assembly - Turntable Position
756806	Cable Assembly - CX4 Sample Turntable
756797	Cable Assembly - SCSI (Instrument to PC)
756798	Cable Assembly - Indicator/Test
756814	Cable Assembly - Barcode Data
758877	Cable, Diagram Terminal
756837	Cable Assembly - P/W Barcode Reader
756838	Cable Assembly - Barcode Trigger
928139	Printer Cable
756832	Cable, RS232 - Host Computer Cable
756779	Cable Assembly - SCSI CX3
895627	Cable Assembly, UPS

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12.3 CX4CE/CX4 DELTA REPLACEMENT PARTS (Continued)

Beckman Part Number	Description
758851	Harness MSB Power
756831	Harness SCSI Power
756818	Harness MMC
756791	Harness AC Power (main power cord for instrument)
756621	ISE Probe Assembly PTS
756858	Tubing Assembly & Sample Probe
467714	SCD, Barcode Reader Head
467715	SCD, Board Assembly Barcode Decoder
756616	Window, Bar Code Reader
895551	Power Socket Strip
946636	Union Bulkhead
946637	Adapter, Stem
946638	Fitting, Stem to Hose
756952	Harness Assembly, Power Monitor
756953	SCSI board (Computer)
464214	Reagent Probe (Conex) - insert
464215	Sample Probe (Conex) - insert
464222	Reagent Probe Cable (Conex)
464223	Sample Probe Cable (Conex)
464110	Muffler Kit (Wash Station insert with O-rings)
759046	Tubing, Reagent Probe to Debubbler
758993	Tubing, Sample Probe to Syringe

12.4 CX4CE/CX4 DELTA REAGENTS/CALIBRATORS/CONTROLS

12.4.1 Reagents

Beckman Part Number	Description
442765	Albumin Reagent, 2 x 300 Test Cartridge
445900	Alcohol Reagent, 2 x 35 Test Cartridge (Includes Calibrator)
442670	ALP Reagent, 2 x 200 Test Cartridge
443799	ALPd Reagent, 2 x 150 Test Cartridge
442620	ALT Reagent, 2 x 200 Test Cartridge
467848	ALT- Reagent, 2 X 100 Test Cartridge
467840	ALT- Reagent, 2 x 300 Test Cartridge
439770	Ammonia Reagent, 2 x 25 Test Cartridge (Includes Calibrator)
445965	Amphetamines (AMPH), 1 x 150 Test Cartridge
442775	Amylase Reagent, 2 x 200 Test Cartridge

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12.4.1 Reagents (Continued)

Beckman Part Number	Description
450101	ASO Reagent, 2 x 70 Test Cartridge
469165	ASO- Reagent, 2 x 100 Test Cartridge
442665	AST Reagent, 2 x 200 Test Cartridge
467849	AST- Reagent, 2 x 100 Test Cartridge
467845	AST- Reagent, 2 x 300 Test Cartridge
445975	Barbiturates (BARB), 1 x 150 Test Cartridge
445980	Benzodiazepine (BENZ), 1 x 150 Test Cartridge
442750	BUN Reagent, 2 x 300 Test Cartridge
442755	Calcium Reagent, 2 x 300 Test Cartridge
445990	Cannabinoids 100 ng (THC), 1 x 150 Test Cartridge
445820	Cannabinoids 50 ng (THC5), 1 x 150 Test Cartridge
445824	Cannabinoids 20 ng (THC2), 1 x 150 Test Cartridge
469112	Carbamazepine Reagent (CAR), 2 x 100 Test Cartridge
467825	Cholesterol Reagent, 2 x 300 Test Cartridge
443797	Cholinesterase (CHE) Reagent, 2 x 100 Test Cartridge
442635	CK Reagent, 2 x 200 Test Cartridge
467830	CK- Reagent, 2 x 200 Test Cartridge
445375	CK-MB, 2 x 60 Test Reagent
443794	CK-Na Reagent, 2 x 200 Test Cartridge
445985	Cocaine Metabolites (COCM), 1 x 150 Test Cartridge
442760	Creatinine Reagent, 2 x 300 Test Cartridge
445855	CRP Reagent, 2 x 100 Test Cartridge
465131	CRP Reagent, 2 x 200 Test Cartridge
442760	CR-T Reagent, 2 x 300 Test Cartridge
439715	D. Bilirubin Reagent, 2 x 200 Test Cartridge
450165	Digoxin Reagent, 1 x 110 Test Cartridge (Includes Calibrator)
469137	Gentamicin Reagent (GEN), 2 x 100 Test Cartridge
442888	Gentamicin Reagent (GENT), 2 x 100 Test Cartridge
442650	GGT Reagent, 2 x 200 Test Cartridge
442640	Glucose Reagent, 2 x 300 Test Cartridge
443796	GOT, 2 x 250 Test Cartridge
443798	GPT, 2 x 250 Test Cartridge
443795	HBDH Reagent, 2 x 200 Test Cartridge
467820	HDL Cholesterol Reagent, 2 x 300 Test Cartridge
442696	IgA Reagent, 2 x 70 Test Cartridge
442697	IgG Reagent, 2 x 70 Test Cartridge
442698	IgM Reagent, 2 x 70 Test Cartridge

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12.4.1 Reagents (Continued)

Beckman Part Number	Description
467910	Iron Reagent (FE), 2 x 200 Test Cartridge
445365	IRON, 2 x 60 Test Cartridge
445875	Lactate Reagent, 2 x 35 Test Cartridge
445391	LAP, 2 x 140 Test Cartridge
443793	LDH Reagent, 2 x 200 Test Cartridge
442655	LD-L Reagent, 2 x 200 Test Cartridge
442660	LD-P Reagent, 2 x 200 Test Cartridge
465101	Lipase Reagent, 3 x 30 Test Cartridge (Includes Calibrator)
465121	Lipase Wash, 2 x 300
445360	Magnesium, 2 x 100 Test Cartridge
445830	Methadone (METD), 1 x 150 Test Cartridge
445835	Methaqualone (METQ), 1 x 150 Test Cartridge
445860	Microprotein Reagent, 2 x 50 Test Cartridge
445960	Opiates (OP), 1 x 150 Test Cartridge
465900	Pancreatic Amylase 2 x 60 Test Cartridge
445840	Phencyclidine (PCP), 1 x 150 Test Cartridge
469785	Phenobarbital Reagent (PHE), 2 x 100 Test Cartridge
442690	Phenobarbital Reagent (PHNB), 2 x 100 Test Cartridge
469188	Phenytoin Reagent (PHY), 2 x 100 Test Cartridge
442893	Phenytoin Reagent (PHNY), 2 x 100 Test Cartridge
442790	Phosphorus Reagent (PHOS), 2 x 300 Test Cartridge
465145	Phosphorus Reagent (PO4), 2 x 300 Test Cartridge
445845	Propoxyphene Reagent (PROX), 1 x 150 Test Cartridge
469985	Rheumatoid Factor (RF), 2 x 100 Test Cartridge
445880	Salicylate Reagent, 2 x 20 Test Cartridge (Includes Calibrator)
442745	T. Bilirubin, 2 x 300 Test Cartridge
469126	Theophylline Reagent (THE), 2 x 100 Test Cartridge
442897	Theophylline Reagent (THEO), 2 x 100 Test Cartridge
465970	Total Iron Binding Capacity Reagent (IBCT), 2 x 100 Test Cartridge
442725	TIBC, 2 x 60 Test Cartridge
445995	T4 Reagent, 1 x 180 Test Cartridge (Includes Calibrator)
467983	Tobramycin Reagent (TOB), 2 x 100 Test Cartridge
442898	Tobramycin Reagent (TOBR), 2 x 100 Test Cartridge
442740	Total Protein Reagent, 2 x 300 Test Cartridge
442699	Transferrin Reagent, 2 x 70 Test Cartridge
445850	Triglyceride GPO Reagent (Blank), 2 x 300 Test Cartridge
445850	Triglyceride GPO Reagent, 2 x 300 Test Cartridge

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12.4.1 Reagents (Continued)

Beckman Part Number	Description
445999	TU Reagent, 1 x 250 Test Cartridge (Includes Calibrator)
442820	Urea Reagent, 2 x 300 Test Cartridge
442785	Uric Acid Reagent, 2 x 300 Test Cartridge
467995	Valproic Acid Reagent (VPA), 2 x 100 Test Cartridge
819247	Lubriplate
589784	Trace-Klean (1 qt)
445967	Antifoam
443735	Probe Rinse Solution (6 x 250 mL)
450160	Wash Concentrate II (2 x 2 L)

12.4.2 Calibrators

Beckman Part Number	Description
442600	CX Multi Calibrator (6 x 20 mL)
450110	CX ASO Calibrator (6 x 1.5 mL)
465915	Total and Direct Bilirubin Calibrator (10 x 1 mL ampules)
445915	CX CRP Calibrator (5 x 1 mL)
467850	CX HDL Cholesterol Calibrator (2 x 10 mL)
469965	CAL 5 Plus Calibrator (ASO-, 2 x 2 mL)
471225	CX RF Cal (6 x 1 mL)
445930	Micro Total Protein Calibrator (10 x 2 mL)
442772	IRON/TIBC Calibrator (2 x 25 mL)
469600	SYNCHRON Drug Cal 1 (6 x 2 mL)
469650	SYNCHRON Drug Cal 3 (6 x 2 mL)
469920	SYNCHRON Drug Cal 4 (6 x 2 mL)
442851	Drug Calibrator, Gentamicin (6 x 3 mL)
442862	Drug Calibrator, Phenytoin/Phenobarbital (6 x 3 mL)
442850	Drug Calibrator, Theophylline (6 x 3 mL)
442876	Drug Calibrator, Tobramycin (6 x 3 mL)
442840	Immuno Protein Calibrator (5 x .5 mL)
442825	Immuno Protein Sample Diluent (6 x 80 mL)
445803	DAT Neg UR Cal (1 x 5 mL)
445801	DAT Low UR Cal (1 x 5 mL)
445802	DAT High UR Cal (1 x 5 mL)
445806	Low UR Cal II (1 x 5 mL)
445807	High UR Cal II (1 x 5 mL)
464390	DAT 20 ng/mL THC UR (1 x 5 mL)

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12.4.2 Calibrators (Continued)

Beckman Part Number	Description
445809	DAT 50 ng/mL THC UR (1 x 5 mL)
445811	DAT 100 ng/mL THC UR (1 x 5 mL)
445814	DAT 200 ng/mL THC UR (1 x 5 mL)
441350	SYNCHRON Enzyme Validator (6 x 5 mL, 3 bottles each of levels 1 & 2)

12.4.3 Controls

Beckman Part Number	Description
657365	SYNCHRON Control, Multilevel Assayed (6 x 20 mL, 2 bottles each of levels 1,2,3)
450162	Vigil Plus Control (3 x 5 mL) Level 1
450163	Vigil Plus Control (3 x 5 mL) Level 2
450164	Vigil Plus Control (3 x 5 mL) Level 3
667710	Ultimate®-D Control, Level 1 (10 x 3 mL)
667720	Ultimate®-D Control, Level 2 (10 x 3 mL)
667730	Ultimate®-D Control, Level 3 (10 x 3 mL)
667740	Ultimate®-D Control, Level 4 (10 x 3 mL)
667990	I.D. Zone CK Control, (6 x 2 mL)
439030	Quanta PHOS® (6 x 5 mL, 2 bottles each of levels 1, 2, 3)
465990	AMM/ALC Control, Level 1 (4 x 4 mL)
465993	AMM/ALC Control, Level 2 (4 x 4 mL)
465996	AMM/ALC Control, Level 3 (4 x 4 mL)
450129	DAT Low Urine Control I (1 x 5 mL)
450134	DAT High Urine Control I (1 x 5 mL)
450144	DAT Low Urine Control II (1 x 5 mL)
450159	DAT High Urine Control II (1 x 5 mL)
465914	20 ng/mL THC Urine Control (1 x 5 mL)
465912	75 ng/mL THC Urine Control (1 x 5 mL)
465939	125 ng/mL THC Urine Control (1 x 5 mL)

12.5 CX3 SUPPLIES

Description
Synchron CX3 DELTA Maintenance Kit
Chloride Maintenance Kit - Sandpaper
Ratio Pump Maintenance Kit - O-rings
Peri-Pump Tubing (Red, pkg. of 12)
Peri-Pump Tubing (Gray, Pkg. of 12)
Peri-Pump Tubing (Green, Pkg of 12)

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12.5 CX3 SUPPLIES (Continued)

Beckman Part Number	Description
669212	Inline Filters (pkg of 10)
928131	Tubing Fittings, Green only
560958	Fitting, Male-molded (union) between red peri pump tubing and inline filter
883728	T-Fitting, Peri-pump
895398	Fitting, Luer Male—barb (top of inline filter)
670597	Glucose Teflon Membranes (pkg of 25)
671488	Glucose Electrode Gel
879049	Silicone Compound
819247	Lubriplate
659895	Membrane Retainer, CO ₂ Measure Electrode
659894	Retainer Clamp, CO ₂ Reference Electrode
661618	Quad Ring Retainer, CO ₂ Reference Electrode
661750	CO ₂ Membranes (pkg. of 5)
669229	Quad Ring Kit (O-rings), (pkg of 4)
443674	Air Filter (Electronics Compartment)
450830	Air Filter (Power Supply Compartment)
041843	Socket-Head Wrench, 3/32-inch
041844	Socket-Head Wrench, 5/64-inch
817304	Socket-Head Wrench, 7/64-inch
817305	Socket-Head Wrench, 9/64-inch
874547	Standard Screwdriver, 5-inch
883364	Phillips Screwdriver, 5-inch
651683	Magnetic Stirrer, Large (CA/Creatine/TP)
651663	Magnetic Stirrer, Small (BUN/Glucose)
671642	Stirrer Removal Tool
450893	Flashlight
669508	Sip Hole Cleaner
450714	Fittings (Plastics), Ratio Pump
439606	Probe Cleaning Kit
467770	Electrolyte Drain Assembly
450626	Flow Cell
467771	Flow Cell (5 port for ISE Calcium)
443628	Damper Assembly
443528	Damper Inlet Fitting
443644	Ratio Pump Assembly
443643	Electrolyte Injection Cup Assembly
450997	Electrolyte Injection Cup Spacer

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12.5 CX3 SUPPLIES (Continued)

Beckman Part Number	Description
946335	Electrolyte Injection Cup Quad Ring
448800	Cover Assembly, Flow Cell, with window
443609	Flow Mixer Electrolyte
443634	Solenoid Pinch Valve
756634	Sample Probe Assembly
464599	Sample Probe Height Tool
467695	Sample Probe Centering Tool
443649	Probe Arm, Crane
756894	Crane Assembly
450822	Cable Assembly, Fluid Sense
450620	Multiple Pinch Valve Assembly—C
450619	Multiple Pinch Valve Assembly—E
450994	Clamp Assembly, E or C Multi Pinch Valve Assembly
448776	Individual Adjustment Screws — E or C Clamp Assembly (Package of 10)
467773	Calcium Module
467774	BUN Module
467772	Creatinine Module
467775	Glucose Module
467776	Total Protein Module
443604	Peri-Pump (Double Tube) Assembly
669192	Peri-Pump (Single Tube) Assembly
668648	Stirrer Motor—Calcium/Creatinine/BUN, (720 rpm)
669662	Stirrer Motor—Glucose/Total Protein, (900 rpm)
659857	Nut Retainer, CO ₂
653504	Nut Retainer, K+
653505	Nut Retainer, Na
660329	Nut Retainer, Cl
660318	CO ₂ Measure/Reference Electrode
441930	Chloride Electrode
447820	Chloride Electrode Cleaning Tool
668295	Sodium Measure/Reference Electrode
443608	Calcium Reference Detector (700 nm)
443607	Calcium Sample Detector (650 nm)
443606	Creatinine Reference Detector (560 nm)
443605	Creatinine Sample Detector (520 nm)
669238	Total Protein Detector (545 nm)
443602	Bichromatic Detector(s) Holder—Calcium/Creatinine

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12.5 CX3 SUPPLIES (Continued)

Beckman	
Part Number	Description
450661	Source Lamp—Calcium/Creatinine/Total Protein
443300	Potassium Electrode (One Piece Electrode)
669115	Potassium/Calcium Electrode Body
669117	Potassium Electrode Tip
467769	Calcium Electrode Tip
651940	BUN Electrode
670522	Glucose Electrode
443624	ADC Board
443623	Analog 2—BUN/Glucose Board
443622	Analog 3—Creatinine/Calcium Board
448699	Analog 3—Creatinine/Total Protein Board
467777	Analog 1—Electrolyte Board
443652	Motion Controller Board
756886	Motion Driver Board No. 1
443651	Motion Driver Board No. 2
443641	Memory Board
467778	CPU Board
467779	IO/SCSI Board (DELTA Systems only)
443637	Disk Controller Board
443572	500 mL Bottle Cap, 1 Outlet
443574	500 mL Bottle Cap, 2 Outlet
669122	Two Liter Bottle Cap, 1 Outlet
440481	Two Liter Bottle Cap, 2 Outlet
443578	Ten Liter (Wash Solution) Bottle Cap
560957	Luer Fitting (Female/Female) for Reagent Line/Cap Assembly
443428	500 mL Bottle, Reagent Pickup Straw
669135	Two Liter Bottle, Reagent Pickup Straw
443429	Ten Liter Bottle, Wash Solution Pickup Straw
828573	Wash Bottle, 10 L
949635	Wrist Strap

12.6 CX3 REAGENTS/CALIBRATORS

Beckman Part Number	Description	
443355	Glucose Reagent, 500 mL	
443350	BUN Reagent, 500 mL	
443340	Creatinine Reagent, 2000 mL x 3	

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12.6 CX3 REAGENTS/CALIBRATORS (Continued)

Beckman Part Number	Description
450224	Total Protein Reagent 1000 mL x 4
450890	Calcium Reagent, 1000 mL
450216	ISE Electrolyte Buffer, 2000 mL
450214	ISE Electrolyte Reference Reagent, 2000 mL
443330	CO ₂ Acid Reagent, 2000 mL
443320	CO ₂ Alkaline Buffer, 500 mL
443335	Wash Concentrate, 250 mL x 6
465908	Calibration Standard, Level 1, 25 mL x 6
465909	Calibration Standard, Level 2, 25 mL x 6
465910	Calibration Standard, Level 3, 25 mL x 6
450202	$SYNCHRON^{\textcircled{8}}$ Systems Protein Calibrators, Levels 1 and 2 with diskette (4 x 5 mL, 2 bottles each)

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Section 13 CX[®] PRO OPERATING INSTRUCTIONS

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13.1 INTRODUCTION

SYNCHRON CX PRO Systems use version 6.0 operating software and are identified with a blue stripe on the outside of the instrument. A general overview of a typical SYNCHRON CX PRO System is described in the following paragraphs. CX PRO operating details and maintenance instructions are described in the following sections of this manual.

13.2 INTENDED USE

SYNCHRON CX4 PRO, CX7 PRO and CX9 PRO systems are similar to other SYNCHRON CX4, CX7, and CX9 systems except they are designed to operate four additional features. Those features include:

- Obstruction Detection and Correction
- Onboard Sample Dilution
- Serum Indices
- Reagent Metering via Modem Connection

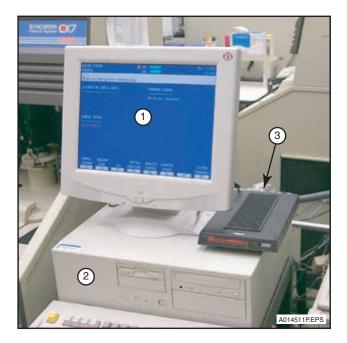
Beckman Coulter SYNCHRON CX Systems are fully automated and computer controlled instruments designed for the vitro diagnostic quantitation of biological fluid components and therapeutic drugs, as well as the qualitative determination of drugs of abuse in urine.

13.3 CX PRO SYSTEM GENERAL DESCRIPTION

13.3.1 CX PRO Software & Hardware

To operate the features listed above, the CX PRO System is equipped with version 6.0 operating software and some internal hardware modifications, including an external modem connection. The CX PRO console has a Pentium microprocessor, a hard drive, a CD-ROM drive, and a floppy disk drive enclosed in a tower case. In addition, each CX PRO system is furnished with a 15 inch flat panel monitor. Refer to Figure 13-1.

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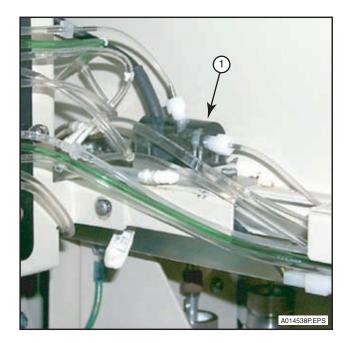
- 1 Flat Panel Monitor
- 2 Pentium Processor
- 3 Modem

Figure 13-1. CX PRO System Hardware Components

13.3.2 CX PRO Obstruction Detection and Correction Feature

CX PRO Systems are able to detect the differences between a normal fluid sample and a clotted sample by measuring the pressure encountered when the samples are aspirated. To accomplish this task, a pressure transducer (shown in Figure 13-2. and Figure 13-3.) is connected to each sample probe assembly. If a clot is detected, the system automatically attempts to remove the clot through two wash cycles. If the clot can not be cleared, sampling from the affected sample probe is stopped and an error message is posted. If the system detects an obstruction for three consecutive samples, the instrument will complete those tasks not affected by the sample probe, and then shut down. For additional information, refer to the CX PRO Operating Instructions section in this manual, or refer to the SYNCHRON CX *Clinical Systems Diagnostic & Troubleshooting Manual* under the CX PRO tab.

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1 - ODC Pressure Transducer

Figure 13-2. Obstruction Detection Pressure Transducer (CX3 Side)



1 - ODC Pressure Transducer

Figure 13-3. Obstruction Detection Pressure Transducer (CX4 Side)

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13.3.3 CX PRO Onboard Sample Dilution Feature

Certain urine and immunoprotein chemistries require the sample to be diluted before analysis. CX PRO System automatically dilutes these samples onboard the instrument using a DIL1 cartridge. The affected chemistries are listed in Table 13-1. For additional information, refer to the appropriate Chemistry Information Sheet inside the SYNCHRON CX Clinical Systems Chemistry Information Manual, Volumes 1, 2, and 3.

Table 13-1. Chemistries Using DIL1 For Onboard Sample Dilution

Urine	Immunoproteins
BUN	IgA
MG	IgG
PHOS	IgM
PO4	TRF
UREA	
URIC	

13.3.4 Manual ORDAC

In addition to the features noted above, the CX PRO System adds MANUAL ORDAC functions for IgA, IgG, IgM and TRF chemistries (1:101 dilution factor). The system also uses the DIL1 cartridge for this function.

13.3.5 CX PRO Serum Indices Feature

The Auto Serum Index/ORDAC function permits the enabling or disabling of the Automatic Serum Index function for all samples. Serum induces can also be enabled or disabled for individual samples. When serum indices are enabled for a sample, hemolysis, icterus, and lipemia indices are automatically determined. A numeric value (index) for the relative concentration (range) is printed below the Special Calculations area of the patient report. Serum indices are intended for sample integrity assessment only, not for patient diagnosis. For additional information, refer to the appropriate Chemistry Information Sheet inside the SYNCHRON CX *Clinical Systems Chemistry Information Manual, Volumes 1, 2, and 3.*

13.3.6 CX PRO Reagent Metering Feature

CX PRO Systems are equipped with an external modem connection to provide a communication interface for reagent metering and system troubleshooting. Reagent metering is described in further detail in the SYNCHRON CX Clinical Systems Metered-Use Manual.

13.4 OPERATING INSTRUCTIONS

This section of the manual describes how to enable and calibrate the Obstruction Detection and Correction (ODC) feature at the CX3 and CX4 side of instrument. In addition, this section also describes various ODC error message that may occur during a typical run.

13.4.1 Enabling the Obstruction Detection and Correction Feature on the CX3 Side (CX7 PRO and CX9 PRO Instruments Only)

To enable the ODC feature on the CX3 side, complete the following steps:

- 1. From the Master screen, press F4 SPECIAL FUNCTION.
- 2. Cursor to "4 System Setup", and press the SELECT key, or type in 4 and press ENTER.
- 3. Cursor to "13 Patient Result Setup/ODC" (shown below), and press the SELECT key, or type in 13 and press ENTER.

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SYSTEM SETUP CONSOLE:	CX3: STANDBY CX4: STANDBY	Nov 15 00 22:25								
Cursor and <select> or enter a number</select>	ber to choose item.									
SYSTEM SETUP OPTIONS										
1. Configure Chemistry Menu 2. Define Chemistry Panels 3. Bar Code Setup 4. Define Reference Ranges 5. Report Setup 6. Special Calculations 7. Units Selection Item Number:	8. Auto Serum Index/ORI 9. Set Date/Time/Tempe: 10. Host Communications 11. Replicates/Statistic 12. Define Comments 13. Patient Result Setup 14. Define Reportable Re	rature Parameters cs p/ODC								
F1 F2 F3 F4	4 F5 F6 F	7 F8								

E014512S.EPS

4. At the Patient Results Setup/ODC screen, cursor to the "CX3 Obstruction Detection" option (shown below) and press the SELECT key to enable. (To disable, press the SELECT key again.)

PATIENT RESULT SETUP CONSOLE:		: STANDBY : STANDBY			Nov 15 00 22:22				
Press <select> to s</select>	et the desired optio	n							
PATIENT RESULT DEFINITIONS									
	Result Approval fo	r Host: [Disabled]					
	Password	Access: [Disabled]					
CX3 I	mmediate Output to P	rinter: [Disabled]					
CX:	3 Immediate Output t	o Host: [Disabled]					
	CX4 Obstruction Det	ection: [Enabled]					
	CX3 Obstruction Det	ection: [Enabled]					
71 70	F2 F4	75	E.C.		70				
F1 F2	F3 F4	F5	F6	F7	F8				

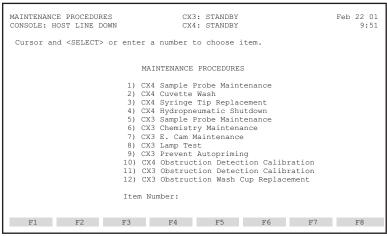
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13.4.2 Calibrating the Obstruction, Detection and Correction Feature on the CX3 Side (CX7 PRO and CX9 PRO Instruments Only)

The first time the CX3 ODC feature is enabled, it must be calibrated. Perform the following CX3 calibration procedure:

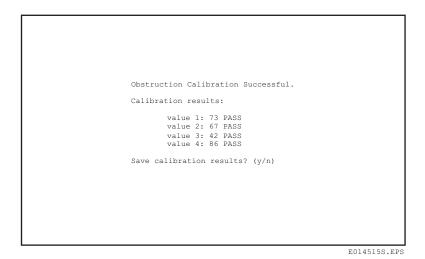
- 1. From the Master screen, press F4 SPECIAL FUNCTION.
- 2. Cursor to "6 Maintenance Procedures" and press the SELECT key, or type in 6 and press ENTER.
- Cursor to "11 CX3 Obstruction Detection Calibration" procedure (shown below) and press the SELECT key, or type in 11 and press ENTER.



E014514S.EPS

- 4. Perform the following CX3 calibration procedure:
 - a. Place saline solution into cup 1 of a sector:
 - b. Load the sector onto sample wheel at slot 1.
 - c. Press "Y" to start the calibration procedure. If you select "N", the system will return to the previous screen.

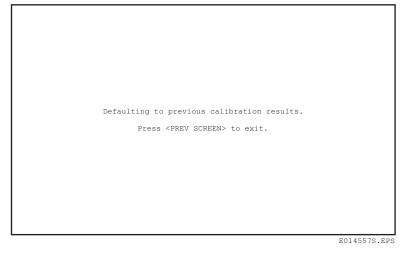
NOTE: When the CX3 Obstruction Detection calibration is completed one of the following messages will appear on the screen.



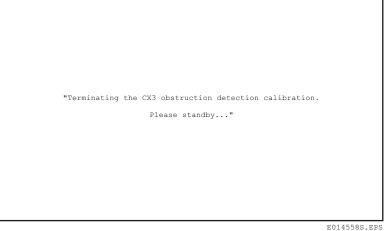
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Obstruction Calibration Failed. Calibration results: value: 73 PASS value: FF FAILED value: FF FAILED value: FF FAILED Press <PREV SCREEN> to exit procedure.

5. If the obstruction detection calibration is successful, press "Y" to save the results. If you select "N", the following message will appear and the system will default to the previous calibration results.



If the PREV SCREEN key is pressed at any time during the calibration procedure, or if the calibration failed and the PREV SCREEN key is pressed, the following message appears on the Master screen:



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6. Repeat the obstruction detection calibration procedure until it passes calibration. If it continues to fail calibration, refer to the SYNCHRON CX *Clinical Systems Diagnostic & Troubleshooting Manual* under the CX PRO tab.

13.4.3 Enabling the Obstruction Detection and Correction Feature on the CX4 Side (CX7 PRO and CX9 PRO Instruments Only)

To enable the ODC feature on the CX4 side, complete the following steps:

- 1. From the Master screen, press F4 SPECIAL FUNCTION.
- 2. Cursor to "4 System Setup" and press the SELECT key, or type in 4 and press ENTER.
- 3. Cursor to "13 Patient Results Setup/ODC" and press the SELECT key, or type in 13 and press ENTER.
- 4. At the Patient Results setup screen, cursor to the "CX4 Obstruction Detection" feature and press the SELECT key to enable. (To disable, press the SELECT key again.)

13.4.4 Calibrating the Obstruction, Detection and Correction Feature in the CX4 Side (CX7 PRO and CX9 PRO Instruments Only)

The first time the CX4 ODC feature is enabled, it must be calibrated. Complete the following calibration procedure:

- 1. From the Master screen, press F4 SPECIAL FUNCTION.
- 2. Cursor to "6 Maintenance Procedures" and press the SELECT key, or type in 6 and press ENTER.
- 3. Cursor to "10 CX4 Obstruction Detection Calibration" and press the SELECT key, or type in 10 and press ENTER.
- 4. Perform the following CX4 calibration procedure:
 - a. Place saline solution into cup 1 of a sector.
 - b. Load the sector onto sample wheel at slot 1.
 - c. Press "Y" to start the calibration procedure. If you select "N", the system will return to the previous screen.

NOTE: When CX4 obstruction detection calibration is completed, one of the following messages will appear on the screen.

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Obstruction Calibration Successful.

Calibration results:

value 1: 73 PASS
value 2: 67 PASS
value 2: 67 PASS
value 3: 42 PASS
value 4: 86 PASS

Save calibration results? (y/n)

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Or,

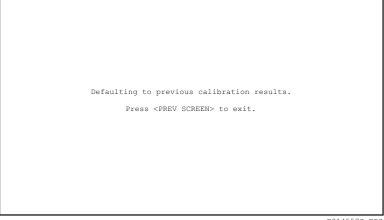
Obstruction Calibration Failed.

Calibration results:

value: 73 PASS
value: FF FAILED

Press <PREV SCREEN> to exit procedure.

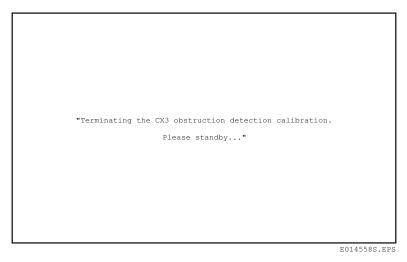
5. If the obstruction detection calibration is successful, press "Y" to save the results. If you select "N" the following message will appear and the system will default to the previous calibration results.



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If the PREV SCREEN key is pressed at any time during the calibration procedure, or if the calibration failed and the PREV SCREEN key is pressed, the following message appears on the Master screen:

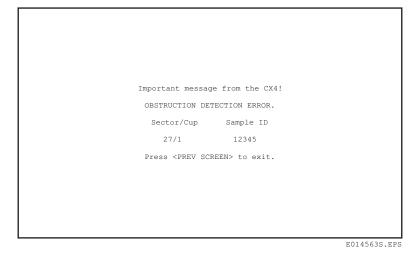
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6. Repeat the obstruction detection calibration procedure until it passes calibration. If it continues to fail calibration, refer to the SYNCHRON CX *Clinical Systems Diagnostic & Troubleshooting Manual* under the CX PRO tab.

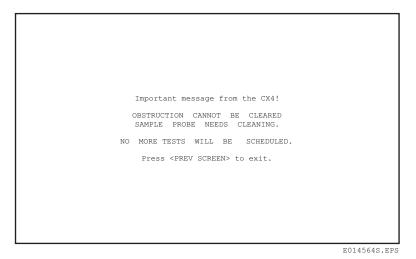
13.5 UNDERSTANDING OBSTRUCTION DETECTION AND CORRECTION ERROR MESSAGES

If an obstruction (clot) is detected in the sample probe at the CX4 side of the instrument, the following error message appears on the Master screen. The system's wash cycle will attempt to clear the clot.

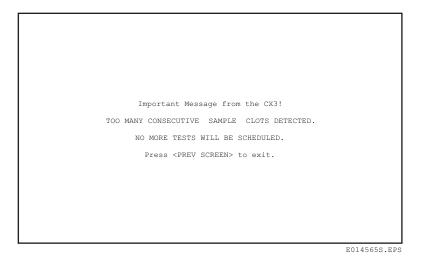


NOTE: If the system is unable to clear the obstruction, the following message appears on the Master screen. The probe must be cleaned. Sampling from the affected sample probe is stopped and no more tests are scheduled.

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NOTE: If the instrument detects an obstruction (clot) on three consecutive samples during a run, the instrument completes those tasks not affected by the sample probe and then shuts down. In this case, the following error message appears on the Master screen. Refer to Section 13.9.1 for additional information.



NOTE

The CX3 side, the CX4 side, or both sides of the instrument (depending on where the clot was detected) will automatically go into a "STANDBY" state. At this point, press the <HOME> key to verify if there are clots in the samples. When the instrument returns to the "STANDBY" state, press the <START> key to resume sample processing.

13.6 ENABLING THE SERUM INDEX FEATURE

When serum indices are enabled for a sample, *hemolysis*, *icterus*, and *lipemia* indices are automatically determined for that sample. The Auto Serum Index feature can be enabled through the System Setup screen. In addition, Serum Index feature can be enabled or disabled for selected samples through Sample Programming screens.

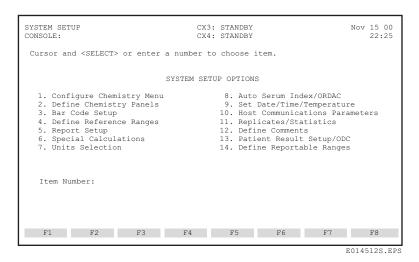
13.6.1 Enabling the Serum Index Feature for All Chemistries

To analyze the samples for all chemistries, enable the Auto Serum Index feature through the System Setup screen as follows:

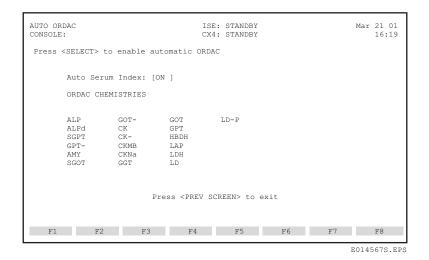
1. From the Master screen, press F4 SPECIAL FUNCTION.

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- 2. Cursor to "4 System Setup", and press the SELECT key, or type in 4 and press ENTER.
- 3. Cursor to "8 Auto Serum Index/ORDAC" option (shown below) and press the SELECT key, or type in 8 and press ENTER.



4. In the AUTO ORDAC screen, cursor to the "Auto Serum Index (ON/OFF] field and press the SELECT key to enable [ON]. (Press the SELECT key again to disable.) This will automatically enable the serum indices feature for all samples. Serum indices can be manually disabled for individual samples through the Sample Programming screen. After the run is completed, the Serum Index results are listed on the patient's report.

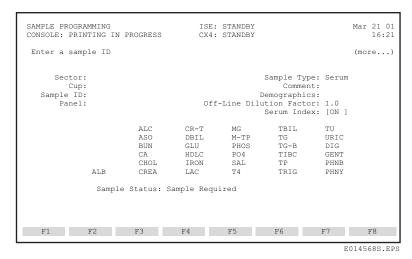


13.6.2 Enabling the Serum Index Feature for Selected Samples

To enable or disable the serum indices for selected samples, complete the following steps:

- 1. From the Master screen, press F1 SAMPLE PROGRAM.
- 2. Select F1 PROGRAM SECTORS, or F2 PROGRAM BATCH. Cursor to appropriate sector/batch number and press the SELECT key, or type in the sector/batch number and press ENTER.
- 3. In the SAMPLE PROGRAMMING screen, cursor to the "Serum Index: [ON/OFF]" field and press the SELECT key to enable [ON]. (To disable [OFF], press the SELECT key again.)

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4. Select the desired chemistries from the list (you cannot program serum indices as a stand-alone test). Selected chemistries will be analyzed automatically for *hemolysis*, *icterus*, and *lipemia* indices. Serum Index results are listed on the patient's report.

13.7 ONBOARD SAMPLE DILUTION FEATURE

As noted in Section 13.3, certain chemistries require the sample to be diluted before analysis. The CX PRO system automatically dilutes these samples using a DIL1 cartridge. The DIL1 cartridge must be loaded onto the instrument to run this feature. Refer to Section 6.2 for loading instructions.

13.8 REAGENT METERING FEATURE

CX PRO Systems utilizes an external modem as the communication interface for reagent metering reagents and other functions. The modem is shown in Figure 13-1. Your Beckman Coulter service representative will set up the modem. Reagent metering instructions are discussed in the *SYNCHRON CX PRO Clinical System Metered-Use Manual* (P/N 968096-AA).

13.9 MAINTENANCE INSTRUCTIONS

Maintenance activities include cleaning the sample probes and replacing the CX3 ODC wash cup.

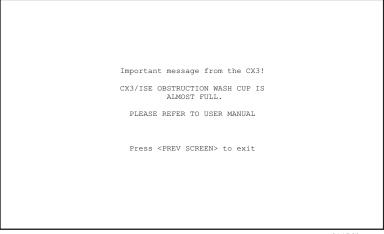
13.9.1 Cleaning the Sample Probes

If the instrument's wash cycle is unable to clear the obstruction (clot) inside the sample probe, the probe must be manually cleaned. To clean the CX3 side sample probe, refer to Section 9.1.9 of this manual for instructions. To clean the sample probe on the CX4 side, refer to Section 9.2.1.

13.9.2 Understanding CX3 Obstruction Wash Cup Messages (CX7 PRO and CX9 PRO instruments only)

When the CX3 instrument probe encounters an obstruction (clot), it will expel the obstruction into a disposable wash cup on the CX3 side of the instrument. The instrument automatically counts the number of times an obstruction is cleared into the wash cup. When the cup is almost full, the following message appears on the Master screen.

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E014569S.EPS

Replace the obstruction wash cup at this time. Refer to Section 13.9.3 for instructions. If the wash cup is not replaced, the following message appears and the instrument automatically goes into a STANDBY condition.

Important message from the CX3!

CX3/ISE OBSTRUCTION WASH CUP IS FULL
PLEASE REFER TO USER MANUAL.

NO MORE TESTS WILL BE SCHEDULED

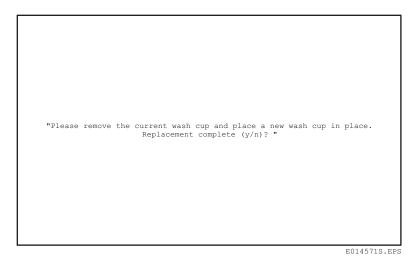
Press <PREV SCREEN> to exit

13.9.3 Replacing the CX3 Obstruction Wash Cup

The CX3 obstruction wash cup is replaced through the Maintenance Procedures. Complete the following steps:

- 1. From the MASTER screen, press F4 SPECIAL FUNCTION.
- 2. Cursor to "6 Maintenance Procedures" and press the SELECT key, or type in 6 and press ENTER.
- 3. Cursor to "12 Obstruction Wash Cup Replacement" option (shown in section 13.4.2) and press the SELECT key, or type in 12 and press ENTER. The following message appears on the screen.

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4. Refer to Figure 13-4. Remove the wash cup (1) from the holder and install a new wash cup (P/N 977230) in place. Be sure the new wash cup is pushed down as far as possible. Discard the old wash cup.

5. When the new wash cup is replaced, press the "Y" key. This lets the system know that the wash cup has been replaced and resets the counter. If "N" is pressed, the counter will not reset.



1 - Obstruction Wash Cup

Figure 13-4. Obstruction Wash Cup

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Call the nearest Beckman Coulter Representative.

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Appendix B INSTRUMENT AND CHEMISTRY CODES

INSTRUMENT CODES

CX4		СХЗ			
CONDITION	CODE	CONDITION	CODE		
Set point modification	M	Set point modification	M		
Slope/offset adjustment	J	Calibration Overridden	С		
Calibration overridden	С	Cal Time extended	Е		
Temperature correction	Т	Cal time modified	Т		
Reagent expired	R	Channel Bypassed	В		
Days exceeded	D	Creatinine Bubble	Р		
Cal time extended	E	DAC Offset	Н		
ORDAC	Ο	Erratic ADC	Α		
Service mode	S	GLU membrane	G		
Rerun sample	V	GLU Initial Conductance	1		
Edited result	Z	No Sample	D		
		Not Run	N		
		ORDAC sample	0		
		Reagent Strength	R		
		Reference Drift	X		
		Service	S		
		Rerun sample	V		
		Edited results	Z		

When the instrument code appears on a report (for example, 05AE), the first three characters designate the chemistry code and the fourth character designates the instrument code as listed above.

CHEMISTRY CODES

01A	= Sodium (NA)	55A	= L	_actate (LAC)
01B	= Potassium (K)	56B	= /	Alcohol (ALC)
02A	= Carbon Dioxide (CO ₂)	57A*	= 8	a-Hydroxybutyrate Dehydrogenase (HBDH)
03A	= Creatinine (CRE)	59A*	= (Cholinesterase (CHE)
03C	= CX3/CX3 DELTA Creatinine (CRE3/CREA)	62A	= [Digoxin (DIG)
03D	= Creatinine Triggered (CR-T)	63A	= 1	Methaqualone (METQ)
04A	= Chloride (CL)	64A	= 1	Methadone (METD)
05A	= Blood Urea Nitrogen (BUN)	65A	= F	Propoxyphene (PROX)
05C	= CX3/CX3 DELTA Blood Urea Nitrogen (BUN3/BUN)	66A	= F	Phencyclidine (PCP)
06A	= Glucose (GLU)	67A	= F	Phenobarbital (PHNB)
06C	= CX3/CX3 DELTA Glucose (GLU3/GLU)	67B	= F	Phenobarbital (PBR)
07A	= Total Protein (TP)	67C	= F	Phenobarbital (PHE)
07B	= Micro Protein (M-TP)	68A	= F	Phenytoin (PHNY)
07C	= CX3/CX3 DELTA Total Protein (TP3/TP)	68C		Phenytoin (PHY)
08A	= Albumin (ALB)	69A		Theophylline (THEO)
09A	= Calcium (CA)	69C		Theophylline (THE)
09C	= CX3/CX7 Cup Calcium (CA3/CA)	70A		Tobramycin (TOBR)
09D	= CX3 DELTA /CX5/CX7 DELTA ISE Calcium (Ca/CALC)	70C		Fobramycin (TOB)
10A	= Amylase (AMY)	71A		Transferrin (TRF)
10B	= Pancreatic Amylase (PAMY)	72A		Gentamicin (GENT)
11A	= Total Bilirumbin (TBIL)	72C		Gentamicin (GEN)
12A	= Direct Bilirubin (DBIL)	73A		Jrea Nitrogen (UREA)
30A	= Aspartate Aminotransferase (AST)	73C		CX3 Urea Nitrogen (URE3)
30B	= Aspartate Aminotransferase-Pyridoxal-5'-Phosphate (AST-)	74A*		Alkaline Phosphatase (ALPd)
31A	= Alanine Aminotransferase (ALT)			Creatine Kinase NAC Buffer (CKNa)
31B	= Alanine Aminotransferase-Pyridoxal-5'-Phosphate (ALT-)			Glutamate Oxalacetate Transaminase (GOT)
32A	= Creatine Kinase (CK)	77A*		Glutamate Pyruvate Transaminase (GPT)
32B	= Creatine Kinase-N-Acetyl-L-Cysteine (CK-)			Lactate Dehydrogenase (LDH)
33A	= Lactate Dehydrogenase (LD-L)	79A		Fotal Iron Binding Capacity (TIBC)
34A	= Lactate Dehydrogenase (LD-P)	79B		Fotal Iron Binding Capacity (IBCT)
35A	= Alkaline Phosphatase (ALP)	82A		Leucine Aminopeptidase (LAP)
36A	= Gamma Glutamyltransferase (GGT)	83A		High Density Lipoprotein Cholesterol (HDLC)
40A	= Creatine Kinase MB (CKMB)	84A		Amphetamines (AMPH)
41A	= Uric Acid (URIC)	85A		Barbiturates (BARB)
42A	= Triglycerides (TRIG)	86A		Benzodiazepine (BENZ)
42B	= Triglycerides GPO (TG)	87A		Cocaine Metabolites (COCM)
42C	= Triglycerides (TG-B)	88A		Cannabinoids - 100ng (THC)
43A	= Inorganic Phosphorus (PHOS)	88B		Cannabinoids - 20ng (THC2)
43B	= Inorganic Phosphorus (PO4)	88C		Cannabinoids - 50ng (THC5)
44A	= Cholesterol (CHOL)	89A		C Reactive Protein (CRP)
46A	= Iron (IRON)	89B		C Reactive Protein (CRP-)
46B	= Iron (FE)	90A		Γ Uptake (TU)
48A	= Magnesium (MG)	91A		Thyroxine (T4)
49A	= Acid Phosphatase (ACP)	92A		Opiates (OP)
50A	= Lipase (LIPA)	93A		Antistreptolysin O (ASO)
50B	= Lipase Wash (LIWA)	93B		Antistreptolysin O (ASO-)
51A	= Immunoglobulin G (IGG)	93C		Rheumatoid Factor (RF)
52A	= Immunoglobulin A (IGA)	94A		Salicylate (SAL)
53A	= Immunoglobulin M (IGM)	95A		Valproic Acid (VPA)
54A	= Ammonia (AMM)	98A	= (Carbamazepine (CAR)

^{*} Deutsche Gesellschaft für Klinische Chemie (German Clinical Chemistry Association) Formulations

NOTE

Chemistry codes for user-defined chemistries correspond to the test name defined for the chemistry on the SYNCHRON CX USER-DEFINED SETUP Screen.

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Appendix C STATUS MATRIX

	CALIBRATION	REAGENT	RESULT	POST-RUN	MASTER	ERROR
CONDITION	STATUS	STATUS	REPORT	SUMMARY	SCREEN	WINDOW
Chemistry bypassed by operator	Chemistry bypassed		Chemistry bypassed	Chemistry bypassed	Chemistry bypassed	
Reagent never previously calibrated; New cartridge	Calibration required		Calibration required	Calibration required	Calibration required	
Operator overrides a "failed" calibration	Overridden		"C" in instr codes		Calibration required	
Attempted calibration failed	Calibration failed		Calibration failed	Calibration failed	Failed calibration	One or more chemistries failed calibration
Calibration timed out but operator wanted to continue running	Cal extended		"E" in instr codes		Cal time extended	
Allowable calibration period exceeded	Cal timed out		Calibration timed out	Calibration timed out	Calibration timed out	
Valid calibration	Calibrated					
Operator selected reagent for calibration	Calibration requested				No cups assigned	
Operator assigned a sector/cup to requested calibration	Requested and assigned					
Operator requested a calibration in bar code mode	Requested and programmed					
Operator selected reagent with same lot number for calibration	Within lot pending		Calibration required	Calibration required	Calibration required	

CONDITION	CALIBRATION STATUS	REAGENT STATUS	RESULT REPORT	POST-RUN SUMMARY	MASTER SCREEN	ERROR WINDOW
Level sense failure (1) motion error (2) no reagent/unexpected level		Level sense error	Level sense error	Level sense error	Level sense error	Reagent level sense error. Check reagent status screen for location.
Reagent not detected at sample inject		Level sense error	No reagent at sample inject	No reagent at sample inject	Level sense error	Reagent not detected at sample inject
While running, available tests decremented to zero		Zero tests available	Reagent cartridge empty	Reagent cartridge empty	Zero tests available	
Shelf-life of reagent has been exceeded		Reagent expired	"R" in instr codes		Reagent date expired	
On board stability exceeded		Days exceeded	"D" in instr codes		Reagent exceeded days usable	
Reagent cartridge not loaded on carousel			Reagent not on board	Reagent not on board	Reagent not on board	
Level sense failed to detect sample in cup			No sample detected	No sample detected		No sample detected
System stopped by operator, hardware or software error			Chemistry not run	Chemistry not run		
Electrolyte reagents low -10% left		Low reagent volume			CX3 reagent volume low	
Temperature changed after calibration	Calibration required		Calibration required	Calibration required	Calibration required	
Motion error during loading or reagent		Pending level check				

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COMBINED INSTRUMENT STATUS

$\leftarrow \textbf{CX3 STATES} \rightarrow$

		Standby	Waiting	Running	Priming	Loading Rgt	Calibrating	Autoprime	Homing	Stopped
	Standby	+	+	+	+	+	+	+	+	+
	Pausing	+	+	+	+	+	+	+	+	+
	Waiting	+	+	+	+	+	+	+	+	+
↑	Running	+	+	+	+	+	+	+	+	+
CX4 STATES	Priming	+	+	+	+	+	+	+	+	+ ^a
\	Loading Reagent	+	+	+	+	+	+	+	+	+ ^a
	Homing	+ ^b	+	()	+	+	+	+	+	+ c
	Idle	+	()	(+	()	(+ (-) ()	()	+	
	Stopping	+	+	+	+	+	+	+	+	+

= Valid combined instrument status

= Invalid combined instrument status

Valid state if CX3 not stopped by EMERG STOP
 Valid state only if CX3 finishes homing first
 Valid under certain conditions, but not a normal state

STANDBY & WAITING States

Before the STANDBY/WAITING combination can be fully understood, an explanation of the individual states is required.

STANDBY means that the instrument is not running and can only be started by pressing the <START> key.

WAITING means that the instrument is not running but may be started automatically without the <START> key being pressed. The instrument can start if a sector is loaded onto the sample carousel which contains samples with tests requested for the WAITING instrument. A WAITING instrument can also be started by creating sample programs for a sample already on the carousel. Sample programs can be created either through the Sample Programming screen on the console or through the host.

NOTE

The WAITING state should not be treated as STANDBY. Don't put your hands near probes or attempt to do anything you wouldn't normally do for a RUNNING instrument. Remember, the state could change to RUNNING without operator intervention. The instrument is really only "waiting" for something to do.

What is STANDBY/WAITING?

The combination of one instrument in STANDBY and the other in WAITING is usually the result of an event or error which prevents the instrument in STANDBY from completing its run normally. The CX7 is basically two separate instruments controlled by the console. When a sample is programmed to run tests on both the CX3 and the CX4, the console splits up the tests into two requests, one sent to the CX3 and one sent to the CX4. Neither the CX3 nor the CX4 know which tests the other is running for the sample. Each individual instrument is only aware of the tests it is requested to perform. It is up to the console to determine when a sample is complete based on the results and other messages received from the CX3 and CX4.

Therefore, when an instrument doesn't complete its run normally, the messages required to complete a sample are not received by the console. This causes those samples which were "in progress" to be held "in progress". The instrument which stopped its run is then set to STANDBY causing the STANDBY/WAITING state.

Note also that the STANDBY/WAITING state can be induced by the operator by using the <PAUSE> key to pause either the CX3 or CX4 (not both, that causes STANDBY).

Some causes of STANDBY/WAITING:

- -CX3 calibrations failed (normal event)
- -CX4 motion control errors (abnormal event)
- —CX4 wash concentrate low (normal event)
- —Any error/condition which causes the CX4 to pause on its own without the operator pressing <PAUSE>

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What Good is STANDBY/WAITING?

The main benefit of the STANDBY/WAITING state is that tests are not aborted for samples on the carousel when the instrument encounters a correctable problem. The status of unfinished samples remains "tests in progress." The operator may then make any necessary corrections to the instrument in STANDBY, press <START>, and the samples will resume testing where they left off.

A good example is an CX3 motion error. Assume that a new run is started with six sectors of seven samples each (42 samples). Each sample has CX3 and CX4 tests requested for it. A CX3 chemistry is also programmed for calibration. The CX3 always runs the calibration brfore sample tests. The calibration fails causing the CX3 to go into STANDBY. The CX4 runs all of its tests and is placed in WAITING by the console because the CX3 test results (which were never run) are required before a sample can be completed. We now have a STANDBY/WAITING situation with all samples having a status of "tests in progress." If the calibration error is correctable (bad or low calibration fluids for example), the operator can fix the problem, press <START>, and the CX3 will run the calibration and complete the tests. The samples will complete and results are printed and sent to the host once.

If the CX4 went to STANDBY instead of WAITING, all the CX3 tests would have been aborted by the console and all 42 samples would become "incomplete," resulting in the printing of 42 sample reports. These samples would have to be run again to complete the CX3 tests. Because of the STANDBY/WAITING state, the CX3 tests are not aborted and the samples only need to run once.

How Do I Get Out of STANDBY/WAITING?

There are three ways to get out of STANDBY/WAITING:

- Option 1. Press the <START> key. The instrument in STANDBY will then start and run any tests it didn't run prior to going into STANDBY. If the problem/event which caused the instrument to go into STANDBY was corrected, the instrument should finish the run and the samples should complete normally. If the problem was not corrected, a STANDBY/WAITING situation could occur again.
- Option 2. Press the <PAUSE> key and pause the WAITING instrument. This will cause both instruments to go into STANDBY. All samples which are "tests in progress" will be set to "incomplete." Any chemistry tests not successfully run will be aborted. This action should be performed whenever option 1 results in another STANDBY/WAITING situation.
- Option 3. Press <EMERGENCY STOP>. This will cause the CX3 to go to STOPPED and the CX4 to go to STANDBY. Samples will be set incomplete and tests aborted as in option 2. This is a harsh way to exit from the STANDBY/WAITING but it will work. Whenever possible, use Option 2 as the preferred method.

Conclusion

The STANDBY/WAITING state is a useful feature which prevents incomplete test results from being printed and sent to the host when an instrument encounters a correctable error during a run. The reasons why the CX7 goes into STANDBY/WAITING are sometimes confusing, but the solution is simple. The <PAUSE> key is pressed to go to STANDBY or the <START> key is pressed to go to RUNNING.

Appendix D DEFAULT UNITS

CHEMISTRY	UNITS	PRECISION
ALB	g/dL	X.X
ALC	mg/dL	Χ
ALP	IU/L	Χ
ALPd	U/L	Χ
ALT	IU/L	Χ
ALT-	IU/L	Χ
AMM	µmol/L	Χ
AMPH	mA/min	X.XX
AMY	U/L	Χ
ASO	IU/mL	X.X
ASO-	IU/mL	X.X
AST	IU/L	Χ
AST-	IU/L	Χ
BARB	mA/min	X.XX
BENZ	mA/min	X.XX
BUN	mg/dL	Χ
CA	mg/dL	X.X
CALC	mg/dL	X.X
CAR	μg/mL	X.X
CHE	U/L	Χ
CHOL	mg/dL	Χ
CK	IU/L	Χ
CK-	IU/L	Χ
CKMB	U/L	X.X
CKNa	U/L	Χ
CL	mmol/L	X.X
CO2	mmol/L	X.X
COCM	mA/min	X.XX
CR-T	mg/dL	X.X
CREA	mg/dL	X.X
CRP	mg/dL	X.X
DBIL	mg/dL	X.X
DIG	ng/mL	X.X
FE	μg/dL	Χ
GEN	μg/mL	X.X
GENT	μg/mL	X.X
GGT	IU/L	Χ
GLU	mg/dL	Χ

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CHEMISTRY	UNITS	PRECISION
GOT	U/L	Χ
GPT	U/L	Χ
HBDH	U/L	Χ
HDLC	mg/dL	Χ
IBCT	μg/dL	Χ
IGA	mg/dL	Χ
IGG	mg/dL	Χ
IGM	mg/dL	Χ
IRON	μg/dL	Χ
K	mmol/L	X.XX
LAC	mmol/L	X.X
LAP	U/L	Χ
LDH	U/L	Χ
LD-L	IU/L	Χ
LD-P	IU/L	Χ
LIPA	U/L	Χ
M-TP	mg/dL	Χ
METD	mA/min	X.XX
METQ	mA/min	X.XX
MG	mg/dL	X.X
NA	mmol/L	X.X
OP	mA/min	X.XX
PAMY	U/L	X
PCP	mA/min	X.XX
PHE	μg/mL	X.X
PHNB	μg/mL	X.X
PHNY	μg/mL	X.X
PHOS	mg/dL	X.X
PHY	μg/mL	X.X
PO4	mg/dL	X.X
PROX	mA/min	X.XX
RF	IU/mL	X
SAL	mg/dL	X.X
T4	μg/dL	X.X
TBIL	mg/dL	X.X
TG	mg/dL	X
TG-B	mg/dL	Χ
THC	mA/min	X.XX
THC2	mA/min	X.XX
THC5	mA/min	X.XX
THE	μg/mL	X.X
THEO	μg/mL	X.X
TIBC	μg/dL	X
TOB	μg/mL	X.X
TOBR	μg/mL	X.X

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CHEMISTRY	UNITS	PRECISION
TP	g/dL	X.X
TP3	g/dL	X.X
TRF	mg/dL	Χ
TRIG	mg/dL	Χ
TU	%	X.X
URE3	mmol/L	X.X
UREA	mmol/L	X.X
URIC	mg/dL	X.X
VPA	μg/mL	X.X

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Appendix E REPORTS

```
17 Aug 95
                                              7:39:39
                                              PAGE 1
                   Lakeview General Hospital
                     1224 Toledo Avenue
                   Lakeview, CA 97111-0000
NAME: JOHNSON, MARY J.
                                SAMPLE ID: 0252113
  PATIENT ID: 555-33-6666
                                SAMPLE TYPE: Serum
       AGE: 35 years
                                    DOCTOR: MARTIN
DATE OF BIRTH: Feb 2 60
                              DRAW DATE/TIME: Aug 16 95 14:00
                               RUN DATE/TIME: Aug 16 95 14:41
       SEX: F
   LOCATION: 234A
                                 SEC/CUP/REP: 4/1
 PAT. COMMENT:
SAMPLE COMMENT: K+ CALLED TO JONES, RN @ 14:59/002.
 INST CODES: Ø1BV Ø5CRZ Ø6CZ
CHEMISTRY
           RESULTS
                    UNITS
                            REFERENCE RANGE REMARKS
NA.
                140 mmol/L 135 - 145
                6.8 mmol/L
104 mmol/L
23 mmol/L
9.1 mg/dL
29 mg/dL
                               3.5 - 5.0
К
                                           CRITICAL HIGH
                            98 - 110
21 - 31
8.2 - 10.2
CL.
002
CALC
BUN-
                                6 - 29
CRE-
                1.5 mg/dL
                               0.5 - 1.3
                                           HIGH
                350 mg/dL
GLU-
                                60 - 115
                                           HIGH
                    g/dL
g/dL
TP-
                6.1
                               6.7 - 8.2
                                            LOW
                              3.5 - 5.0
2.5 - 4.5
100 - 210
115 - 250
ALB
                3.1
                                            LOW
                    mg/dL
PHOS
                1.9
                                            LOW
CHOL
                203 mg/dL
TG
                172 mg/dL
                 80 IŪ/L
23 IU/L
ALP
                                35 - 100
AST
                                 8 - 45
                 76 IU/L
                                50 - 250
CK
-BHCG QUAL
             NEGATIVE
                                 * -- *
CALCULATED VALUES RESULTS UNITS
                             REFERENCE RANGE
                                            REMARKS
 ANION GAP (1)
               13.0
                                6.0 - 16.0
A 05143C.EPS
```

Figure E-1. Chart Report, Format A

17 Aug 95 7:40:29 PAGE 1 Lakeview General Hospital 1224 Taledo Avenue Lakeview, CA 97111-0000 NAME: JOHNSON, MARY J. SAMPLE ID: 0252113 PATIENT ID: 555-33-6666 SAMPLE TYPE: Serum AGE: 35 years DOCTOR: MARTIN DATE OF BIRTH: Feb 2 60 DRAW DATE/TIME: Aug 16 95 14:00 RUN DATE/TIME: Aug 16 95 14:41 SEX: F LOCATION: 234A SEC/CUP/REP: 4/1 PAT. COMMENT: SAMPLE COMMENT: K+ CALLED TO JONES, RN @ 14:59/002. INST CODES: Ø1BV Ø5CRZ Ø6CZ UNITS REF RANGE CHEMISTRY RESULTS _____ LOW NORMAL HIGH NA 140 mmol/L 135 - 1456.8(!) mmol/L К 3.5 - 5.0CL 104 mmo1/L 98 - 110 coa 23 mmol/∟ 21 - 31 mg/dL mg/dL 1.5 mg/dL 350 mg/dL CALC 9.1 8.2 - 10.2 6 - 29 BUN-29 CRE-0.5 - 1.3 GLU-60 - 115 TPg/dL 6.1 6.7 - 8.2 3.5 - 5.0 ALB 3.1 ց/ժև mg/dL 2.5 - 4.5 PHOS 1.9 CHOL 203 mg/dL 100 - 210 115 - 250TG 172 mg/dL ALP. 35 - 100 80 IU/L AST 23 IU/L 8 - 45 CK 76 50 - 250 IU/L -BHCG QUAL NEGATIVE * -- * CALCULATED VALUES RESULTS UNITS REFERENCE RANGE REMARKS ______ ANION GAP (1) 13.0 6.0 - 16.0A 05144C.EPS

Figure E-2. Chart Report, Format B

E-2 November 1995 248408-G

	***			17 Aug 95 14:26:58 PAGE 1
		1224 Tol	neral Hospital ledo Avenue CA 97111-0000	
PATIENT ID: AGE: DATE OF BIRTH: SEX: LOCATION: PAT. COMMENT:	F	J.	DOCTOR: DRAW DATE/TIME:	Random Urine MARTIN Aug 17 95 13:45 Aug 17 95 14:16
SAMPLE COMMENT: INST CODES:				
INST CODES:	RESULTS	 UNITS	REFERENCE RANGE	======================================
INST CODES:			REFERENCE RANGE 40 - 220	REMARKS
INST CODES:	112	mmol/L		QUALITATIVE
	112	mmol/L UNITS mA/min	40 - 220 CUT-OFF RATE 553.45	QUALITATIVE

Figure E-3. Chart Report with DAT Chemistries

17 Aug 95 7:40:52 PAGE 1

A_05146C.EPS

CUP: 1

Lakeview General Hospital 1224 Toledo Avenue Lakeview, CA 97111-0000

SECTOR: 4

RUN DATE/TIME: Aug 16 95 14:41 SAMPLE ID: 0252113 SAMPLE TYPE: Serum

CHEM		RESULTS		REFERENCE RANGE	REMARKS
NA				135 - 145	
K		6.8 (R)	mmol/L	3.5 - 5.0	CRITICAL HIGH
CL		104	mmol/L	98 - 110	
202		23	mme1/L	21 - 31	
CALC		9. i	mg/dL	8.2 - 1 0. 2	
BUNG		29 (E)		6 - 29	
CRE3		1.5		0.5 - 1.3	HIGH
GLU3		350 (E)		60 - 115	HIGH
TP3		6.1	g/dL	6.7 - 8.2	LOW
ALB		6. 1 3. 1	g/dL	3.5 - 5.0	LOW
PHOS		1.9	mg/dL	2.5 - 4.5	LOM .
CHOL		203		100 - 210	
TG			mg/dL	115 - 250	
JLF:		80		35 100	
AST		23		8 - 45	
CK	(1)	76	IU/L	50 - 250	
- BHCG	QUAL	NEGATIVE		* - *	
CALC '				REFERENCE RANGE	
ANION		13.0		6.0 - 16.0	
	SAMPLE CO	MMENTS		INSTRU	MENT CODES
K+ CA! 9 14:5	LED TO JO 59/002.	DNES, RN		Ø1BV Ø5CRZ Ø6	5CZ ·
	ITED: 202				

Figure E-4. Laboratory Format

E-4 November 1995 248408-G

						17 Aug 95 7:41:10 PAGE 1
			La	eview General 1224 Toledo keview, CA 97	Avenue 111-0000	
RUN DATE SAMPI SAMPLE DILU	/TIME: LE ID: TYPE: TIONS:	Aug 16 95 0252113 Serum	14:4	1		ECTOR: 4 CUP: 1
CHEM LO	С	RESULTS			REFERENCE RANGE	
NA K CL CO2 CALC BUN3		140 6.8 104 23	(R)	mmol/L mmol/L mmol/L mmol/L mg/dL mg/dL	135 - 145 3.5 - 5.0 98 - 110 21 - 31 8.2 - 10.2 6 - 29	CRITICAL HIGH
CRE3 SLU3 TP3 ALB (5 PHOS (7 CHOL (4 TG (3 ALP (2)))	1.5 350 6.1 3.1 1.9	(E)	mg/dL mg/dL	0.5 - 1.3 60 - 115 6.7 - 8.2 3.5 - 5.0 2.5 - 4.5 100 - 210 115 - 250 35 - 100	HIGH LOW LOW LOW
AST (6 CK (1 -BHCG QU		23 76 NEGATIVE		IU/L IU/L	8 - 45 50 - 250 * - *	
					REFERENCE RANGE	REMARKS
		13.0		1000 HOT THE SILE HIT THE SILE HER SILE HIS HER HIT HER	6.0 - 16.0	. Alle ball 1879 tale den Sale 1881 bliv alle aut bale aut au
SAM	PLE COM	MENTS			INSTRU	MENT CODES
K+ CALLE 9 14:59/		NES, RN			Ø1BV Ø5CRZ Ø	16CZ -
				ISE ADC RESUL	.TS	
CHEM	SAMPL REF		LE	SAMPLE DEVIATION	REF SOLUTION	REF SOLUTION DEVIATION
NA K CL CO2 CALC	-33 -33 -2 55 -23	4 6 5 3 0 -3358	16 01 /-221	1 Ø Ø 6	-1767 950 326 -3471/-2879 -580	Ø Ø J
						A_05147C.I

Figure E-5a. Laboratory Format with ADC/ABS (Page 1 of 2)

17 Aug 95 7:41:10 PAGE 2 Lakeview General Hospital 1224 Toledo Avenue Lakeview, CA 97111-0000 RUN DATE/TIME: Aug 16 95 14:41 SECTOR: 4 SAMPLE ID: 0852113 CUP: 1 SAMPLE TYPE: Serum DILUTIONS: NON ISE ADC RESULTS RATE DELTA ABS FINAL READ GAIN INIT READ _____ BUN3 40195 2368 -109 75≳ CRE3 3548 GLU3 -1959 -1775 TP3 -554 111 -124 EXPANDED ABSORBANCE RESULTS BLANK REACTION CHEM CUVETTE NO BLANK DEVIATION REACTION DEVIATION 0.38292 0.58819 ALB 1 PHOS 80 CHOL 76 TG

 Ø. 14485
 Ø. ØØØ18

 Ø. 528ØØ
 Ø. ØØØ82

 Ø. ØØ587
 Ø. ØØØ14

 Ø. Ø9267
 Ø. ØØØ34

 ଡ. ଉଷ୍ଟର୍ଷ PHL CHOL TG ALP 9ST 79 78 0.00031 0.00009 Ø. 14525 0.00587 Ø. Ø9267 0.26856 **0.**00026 0.00112 0.00007 0.01474 0.00012 -0.00608 0.01122 0.00088 0.00004 0.00012 Ø. ØØØ36 0.00003 Ø. 00007 EDITED: 002 A 05148C.EPS

Figure E-5b. Laboratory Format with ADC/ABS (Page 2 of 2)

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17 Aug 95 7:41:30 PAGE 1

A_05149C.EPS

Lakeview General Hospital 1224 Toledo Avenue Lakeview, CA 97111-0000

RUN DATE/TIME: Aug 16 95 14:41 SAMPLE ID: 0252113

SECTOR: 4 CUP: 1

SAMPLE TYPE: Serum

DILUTIONS:

	========				
				REFERENCE RANGE	REMARKS
				4 75 4 75	
NA				135 - 145	
K.				3.5 - 5.0	CRITICAL HIGH
CL		1 🛭 4		98 - 110	
002		23	mmol/L	21 - 31	
CALC		9.1	mg/dL	8.2 - 10.2	
BUN3		29 (E)	mg/dL	£ - 29	
CRE3		1.5	mg/dL	0.5 - 1.3	HIGH
GLU3		350 (E)	mg/dL	60 - 115	HIGH
TP3		6.1	_	6.7 - 8.2	
AL.B	(5)	3.1		3.5 - 5.0	
PHOS	(7)	1.9		2.5 - 4.5	
CHOL		203		100 - 210	
TG		172		115 - 250	
ALP		80		35 - 100	
AST		23		8 - 45	
CK		76		50 - 250	
- BHCG	QUAL	NEGATIVE		* - *	
CALC	VALUES	RESULTS	UNITS	REFERENCE RANGE	REMARKS
ANT ON					
HIATON	DHF (1)	13.0		6.0 - 16.0	

SAMPLE COMMENTS INSTRUMENT CODES K+ CALLED TO JONES, RN Ø1BV Ø5CRZ Ø6CZ

@ 14:59/002.

ISE ADC RESULTS

CHEM	SAMPLE REF	SAMPLE	SAMPLE DEVIATION	REF SOLUTION	REF SOLUTION DEVIATION
NA	36	-1731	1	-1767	12
K	-334	616	Ø.	950	Ø
CL	-25	301	12)	326	1
C02	550	-3358/-2216		-3471/-2879	
CALC	-239	-819	1	-580	

Figure E-6a. Laboratory Format with Raw Data (Page 1 of 3)

17 Aug 95 7:41:30 PAGE 2 Lakeview General Hospital 1224 Toledo Avenue Lakeview, CA 97111-0000 RUN DATE/TIME: Aug 16 95 14:41 SECTOR: 4 SAMPLE ID: 0252113 CUP: 1 SAMPLE TYPE: Serum DILUTIONS: NON ISE ADC RESULTS CHEM RATE DELTA ABS INIT READ FINAL READ GAIN BUN3 4095 2368 -109 DRE3 3548 GLU3 752 -1959 -1775 TP3 -554 111 -124 RAW ADC DATA ALB INIT ABS 0.37904 FINL ABS 0.38311 RAW RES 0.83807 CUVETTE# 1 WATER BLANK REACTION NOISE ABS -0.32851 ABS 0.14485 ABS 0.38292 MAX 1
RATE 1.0 RATE 0.00088 RATE 0.00177 OUTL MAX 3
MEAN DEV 35.0 MEAN DEV 0.00018 MEAN DEV 0.00006 THR TOT 0
MAX DEV 85.0 MAX DEV 0.0005 MAX DEV 0.00025 OUTL TOT 0 PHOS INIT ABS 0.58454 FINL ABS 0.58942 RAW RES 0.06019 CUVETTE# 80 NOISE
 WATER
 BLANK
 REACTION
 NOISE

 ABS
 1.4763
 ABS
 0.528
 ABS
 0.58819
 MAX
 3

 RATE
 0.0
 RATE
 -0.00549
 RATE
 0.00516
 OUTL MAX
 5

 MEAN DEV
 34.0
 MEAN DEV
 0.00082
 MEAN DEV
 0.00081
 THR TOT
 0

 MAX DEV
 68.0
 MAX DEV
 0.00163
 MAX DEV
 0.00081
 OUTL TOT
 0
 CHOL INIT ABS 0.00539 FINL ABS 0.14801 RAW RES 0.13937 CUVETTE# 76 FINL BLANK -Ø.20761 ABS -7.0 REACTION WATER NOISE ABS -0.20761 ABS 0.00587 ABS 0.14525
RATE -7.0 RATE 0.00024 RATE 0.01105
MEAN DEV 28.0 MEAN DEV 0.00014 MEAN DEV 0.00009
MAX DEV 64.0 MAX DEV 0.00027 MAX DEV 0.00022 0.14525 MAX OUTL MAX 1 THR TOT @ OUTL TOT @ TG INIT ABS 0.09444 FINL ABS 0.26832
 WHITER
 BLANK
 REACTION
 NOISE

 ABS
 0.01128
 ABS
 0.09267
 ABS
 0.26856
 MAX
 2

 RATE
 -15.0
 RATE
 0.00191
 RATE
 -0.00321
 OUTL MAX
 4

 MEAN DEV
 30.0034
 MEAN DEV
 0.00077
 MOX
 DEV
 0.00026
 THR
 TOT
 0
 RAW RES 0.17589 CUVETTE#: 75

Figure E-6b. Laboratory Format with Raw Data (Page 2 of 3)

E-8 November 1995 248408-G

A 05150C.EPS

	EXPLANATION OF RAW DATA ABBREVIATIONS
INIT ABS	The reaction absorbance data taken during the first spin cycle after sample inject or trigger cycle.
FINAL ABS	The reaction absorbance data taken during the read window.
RAW RESULT	The flash-corrected absorbance result used in the calculation of the final results (refer to Paragraph 4.4.3)
CUVETTE #	Number of cuvette in which reaction is taking place.
ABS	Mean absorbance measured during spin cycles with the appropriate sample in the cuvette (water, reagent, reagent and sample).
RATE	For water and blank this is the endogenous rate calculated during the water or reagent blank spin cycles. For reaction this is the rate calculated during the reaction read window.
MEAN DEV	The average difference between the absorbance readings and the line of regression for that data.
MAX DEV	The largest deviation of an absorbance from the mean absorbance after data smoothing. Measured over the respective timing window (blank and absorbance).
MAX	The absorbance (mABS) of the largest MEAN DEV of a cycle in the blank and reaction windows.
OUTL MAX	The largest deviation of a data point from the line of regression of all data points in a cycle.
THR TOT	Maximum allowable number of cycles that the MAX value exceeded the threshold value in the database.
OUTL TOT	Maximum allowable number of cycles that the OUTL MAX value exceeded the threshold value in the database.

Figure E-6c. Laboratory Format with Raw Data (Page 3 of 3)

```
18 Aug 95
                                                     8:17:42
                                                    PAGE 1
                   CX7 DELTA RESULT SUMMARY REPORT
     SAMPLE TYPE:
                                         FLAGS:
      S = Serum
                                *H* = Above reference range
      P = Plasma
                                *L* = Below reference range
      C = CSF
                                *!* = Critical value
      TU = Timed Urine
                                *** = No reference range defined
                                *S* = Suppressed result
      RU = Random Urine
                                (+) = Positive result (Drug of Abuse)
                                (-) = Negative result (Drug of Abuse)
NAME: MARTINEZ, JUAN I. PAT_ID: 111-99-4444 REP: 1
S/C: 55/1 INIT RUN DATE: Aug 18 95 8:16:00 FLUID: S SMP_ID: 0260112
 COMMENT:
                                       LOC: OPD
INST CODES:
DILUTIONS: GLU3:2.0
GLU3 *H* 251 mg/dL
NAME: LEE, THOMAS M. PAT_ID: 777-99-4455 REP: 1
S/C: 55/3 INIT RUN DATE: Aug 18 95 8:16:01 FLUID: S SMP_ID: 0260334
  COMMENT:
                                       LOC: 267A
INST CODES:
DILUTIONS:
         33 mg/dL | GLU3 111 mg/dL | CRE3 *H*
6.1 g/dL | CL 109 mmol/L | CO2
6.9 mmol/L | NA *H* 148 mmol/L | CALC
BUN3 *H*
                                                        1.4 mg/dL
TP3 *L*
                                                        23 mmol/L
                                                        9.5 mg/dL
K *!*
OSMOLALITY (1) *** 302.2 mOsm/L
ANION GAP (1) 16.0
NAME: STEINBERG, LINDA PAT_ID: 777-44-1111 REP: 1
         INIT RUN DATE: Aug 18 95 8:16:00 FLUID: S SMP_ID: 0260223
S/C: 55/2
                                        LOC: 345B
  COMMENT:
INST CODES: 01BV 09DV
DILUTIONS:
           8 mg/dL | GLU3 104 mg/dL | CRE3 0.5 mg/dL
4.6 g/dL | ALB *L* 2.6 g/dL | CL 103 mmol/L
25 mmol/L | K 4.3 mmol/L | NA *H* 146 mmol/L
BUN3
TP3 *L*
          25 mmc1/L | K 4.3 mmc1/
8.7 mg/dL | AST 26 IU/L
002
CALC
         OSMOLALITY (1) *** 289.2 mOsm/L
ANION GAP (1) *H* 18.0
```

Figure E-7. Result Summary Report

E-10 November 1995 248408-G

							17 Aug 95 7:42:27 PAGE 1
			Lakevie	w General Hosp	ital		
				¥ Toledo Avenu	**		
				ew, CA 97111-0			
		HNSON, MARY J				TOR: MARTIN	
		3-33-6666	•			10N: 234A	
	3E: 35					SEX: F	
DATE OF BIR		,				DENT .	
COMME							
DRAW DA				Aug 16 95		 Aug 16 95	======================================
DRAW TI				15:00		14:00	
SAMPLE					0252257	0252113	
SAMPLE TY					Serum	Serum	
DILUTI	DN: ()	= Off-Line D)ilution	(Yeş)		20. 2	
SAMPLE COMME	NT:			HEMOLYZED		K+ CALLED	Т
CHEMISTRY	REF	RANGE	UNITS	RESULTS	RESULTS		RESULTS
 NA	135	- 145	mmol/L	# 14: # 4:		140	
K	3.5	- 5.0	mmol/L		6.0	6.8	
CL	98	- 110	mmol/L			104	
002	21	- 31	mmol/∟			23	
CALC		- 10.2	mg/dL			9.1	
BUN-		- 29	mg/dL			19	
CRE-		- 1.3	mg/dL			1.5	
GLU-		- 115	տց/d⊾	(737)		350	
TP-		- 8.2	g/dL			6.1	
ALB BURG		- 5.0	g/dL			3.1	
PHOS CHOL		- 4.5 - 210	mg/dL			1.9	
CHOL TG		- 250	mg/dL mg/dL			203 172	
ALP		- 100	#y/or IU/L			172 80	
AST		- 45	IU/L			23	
CK		- 250	IU/L			76	
-BHCG QUA		- *	10/ 0			NEGATIVE	
CALCULATED VA							•
ANION GAP (1)		6.0 - 16.0				13.0	

Figure E-8. Patient Multi-Sample Report

25 May 95 11:09:37 PAGE 1

A_05085C.EPS

CX4 PRE RUN SUMMARY REPORT

REAG LOC	CHEM	TESTS AVAIL	REAG STATUS	CAL STATUS
1 2 3 4 5 6 7 8 9	CHEM UREA CA CREA GLU IGM LD-L TBIL TG ALP DBIL	306 317 355 291 21 210 302 297 201	STATUS Ok	Calibrated Calibrated Calibrated Calibrated Calibrated Calibrated No Calibration Calibrated Calibrated Calibrated Calibrated Calibrated Calibrated No Calibrated
11 12 13 14 15 16 17 18 19 20 21	AST CK	217 213 121 308 341	0k 0k 0k 0k 0k 0k	No Calibration No Calibration Calibrated Calibrated Calibrated Calibrated Calibrated
23 24	ALT	195	Ok	No Calibration

CX4 RESIDENT TEST SUMMARY

CHEM	TESTS PROGD	TOTAL AVAIL
UREA	2	306
CA	2	317
CREA	2	355
GLU	2	291
IGM	Ø	21
LD-L	3	210
TBIL	4	302
TG	2	297
ALP	3	201
DBIL	i	201
AST	2	217

Figure E-9a. Pre-Run Summary Report (Page 1 of 3)

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			25 May 95 11:09:37 PAGE 2
	IDENT TEST		
CHEM 	TESTS PROGD	TOTAL AVAIL	
CK MG PHOS ALB	ହ ଉ ଉ	213 121 308 341	
CHOL ALT	Ø 1	314 195	
— — — m m as as as	TE	STS	
CX4 NON-R	TE M PR		
CHE	TE M PR 	STS OGD	
CHE AMY CKM GGT PAM	TE M PR Ø B Ø V Ø	STS OGD	
CHE AMY CKM GGT	TE PR	STS OGD	
CHE AMY CKM GGT PAM LAP HBD IGG IGA GEN	TEM PR 0	STS OGD	
CHE AMY CKM GGT PAM LAP HBD IGG	TEM PR 0	STS OGD	
CHE AMY CKM GGT PAM LAP HBD IGG IGA GEN TOB MET T4 COC	TEM PR	STS OGD	
CHE AMY CKM GGT PAM LAP HBD IGG IGA GEN TOB MET T4	TEM PR 0 0 0 0 0 0 0 0 0 0 0 0 0	STS OGD	

Figure E-9b. Pre-Run Summary Report (Page 2 of 3)

						25 May 95 11:09:37 PAGE 3
		(CX3 PRE RUN SU		PORT	
CHEM	TESTS PROGD		REAG STATUS		CAL STATUS	
NA	9	Ok			Calibrated	
K	6	Ok			Calibrated	
CL	6	Ok			Calibrated	
002	6	Ωk			Calibrated	
BUN3	6	79%			Calibrated	
GLU3	9	80%			Calibrated	
	6	54%			Calibrated	
TP3 		87%			Calibrated	
		(ELECTROLYTE RE	AGENT SI	ATUS	
	REAGENT		VOLUME (%)	ere un un in_	STATUS	
Electro	olyte Buffe	r	94	Ok		
Electro	olyte Refer		96	Ok		
CO2 Ac:	id		96	Ok		

Figure E-9c. Pre-Run Summary Report (Page 3 of 3)

E-14 November 1995 248408-G

				25 May 95 12:43:01 PAGE 1
	CX7 DELTA	POST RUN SU	IMMARY REPORT	
DATE - TIME PROGD		ECT PEND CUP CHEM	STATUS	may reps total tilds alone one ones seps plats a
25 May 95 10:52	Ø123579	1/6 GLU 3	CHEM NEEDS SAMPLE	A_05088C.EPS

Figure E-10. Post-Run Summary Report

13 Jul 95 11:13:18 PAGE 1 CALIBRATION VERIFICATION REPORT Lakeview General Hospital Critical Care Unit Building 1 1224 Toledo Avenue UNITS: mmol/L CHEMISTRY: NA REAGENT LOT: N/A REAGENT SERIAL: CALIBRATOR LOT: SET NAME: LYTES-VERIFIER SET LOT: L41195 RUN DATE/TIME: Jul 13 95 10:49 INSTRUMENT CODES: LEVEL RANGE MEAN COMMENT 95.00 - 105.00 101.22 1 3 143.00 - 157.00 152, 29 4 5 190.00 - 210.00 202.01 6 LEVEL: 2 3 4 5 6 TARGET: 100.00 150.00 200.00 REP1: 101.39 152.12 202.32 REP2: 100.85 153.10 201.47 REP3: 101.46 151.79 201.61 REP4: 101.31 152.55 202.18 REP5: 101.08 151.90 202.46 MEAN: 101.22 152, 29 202.01 REVIEWED BY: _____ DATE: ____ COMMENTS: Sample Status LEVEL 1: LEVEL 2: LEVEL 3: LEVEL 4: LEVEL 5: LEVEL 6: LEVEL 7: A_05128C.EPS

Figure E-11a. Calculation Verification/Linearity Report (Page 1 of 3)

E-16 November 1995 248408-G

```
13 Jul 95
                                                    11:13:21
                                                    PAGE 1
                     LINEARITY REPORT
                     Lakeview General Hospital
                     Critical Care Unit
                     Building 1
                      1224 Toledo Avenue
                CHEMISTRY: NA
                                   UNITS: mmo1/L
             REAGENT LOT: N/A
                               REAGENT SERIAL:
                 CALIBRATOR LOT:
         SET NAME: LYTES-VERIFIER
                                      SET LOT: L41195
                  RUN DATE/TIME: Jul 13 95 10:49
INSTRUMENT CODES:
2
                                                  5
                                                            6
 %DIL:
TARGET:
           100.00
                    125.00
                             150.00
                                        175.00
                                                  200.00
 REP1:
           101.39
                    127.39
                             152.12
                                        176.85
                                                  202.32
 REP2:
           100.85
                    126.74
                             153.10
                                        176.72
                                                  201.47
 REP3:
           101.46
                    127.49
                             151.79
                                        176.60
                                                  201.61
 REP4:
           101.31
                    127.02
                             152, 55
                                        176.35
                                                  202.18
 REP5:
           101.08
                    127.11
                             151.90
                                        176.72
                                                 202.46
           101.22 127.15 152.29
0.25 0.30 0.54
 MEAN:
                                        176.65 202.01
   SD:
                                         Ø. 19
                                                  0.44
REVIEWED BY: _____ DATE: ____
COMMENTS:
Sample Status
LEVEL 1:
LEVEL 2:
LEVEL 3:
LEVEL 4:
LEVEL 5:
LEVEL 6:
LEVEL 7:
                                                                      A 05129C.EPS
```

Figure E-11b. Calculation Verification/Linearity Report (Page 2 of 3)

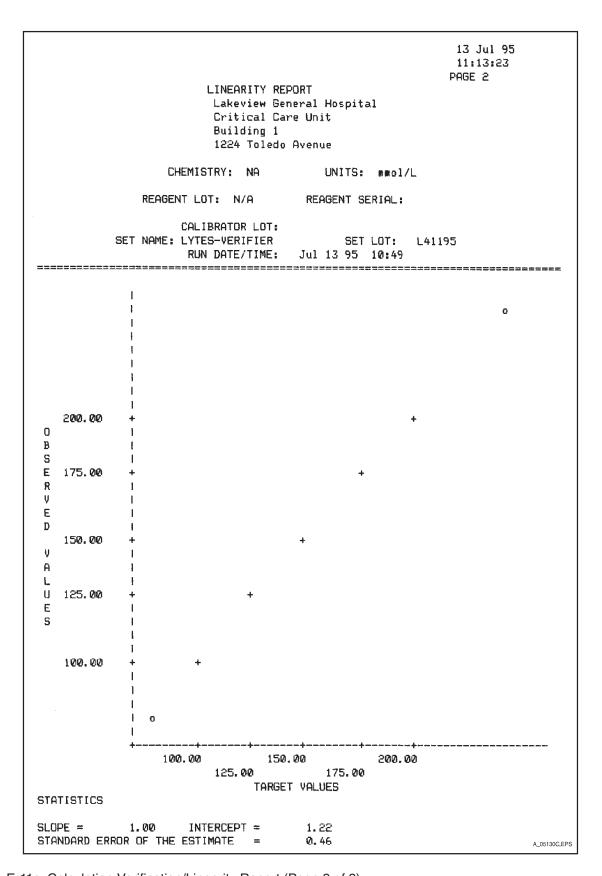


Figure E-11c. Calculation Verification/Linearity Report (Page 3 of 3)

E-18 November 1995 248408-G

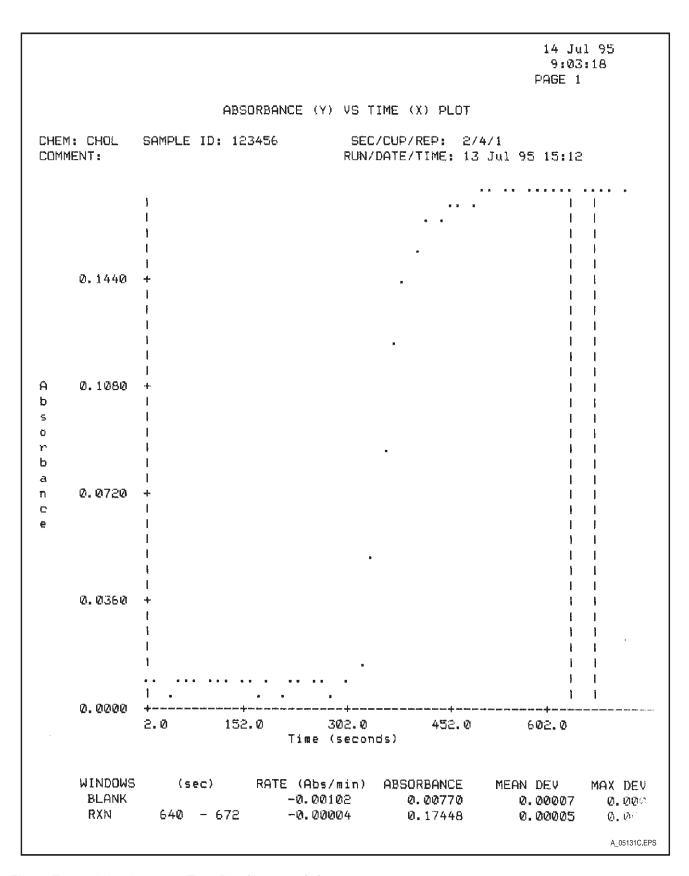


Figure E-12a. Absorbance vs Time Plot (Page 1 of 2)

		14 Jul 9 9:03:18 PAGE 2
	ABSORBANCE	(Y) VS TIME (X) TABLE
CHEM: CHOL COMMENT:	SAMPLE ID: 123456	SEC/CUP/REP: 2/4/1 RUN/DATE/TIME: 13 Jul 95 15:12
SECONDS	ABSORBANCE	SECONDS ABSORBANCE
3.0	Ø. ØØ7 9 6	643.0 0.17454
19.0	0.00785	659.0 0.17444
35.0	0.00743	675.0 0.17454
51.0	0.00774	691.0 0.17454
67.Ø	0.00817	707.0 0.17476
83.Ø	0.00785	723.0 0.17476
99.0	0.00774	
115.0	0.00785	
131.0	0.00817	
147.0	0.00785	
163.0	Ø. ØØ785	
179.0	0.00753	
195.0	Ø. ØØ785	
211.0	0.00764	
227.0	Ø. ØØ785	
243.0	0.00828	
259.0	Ø. ØØ796	
275.Ø	0.00774	
291.0	0.00732	
307.0	Ø. ØØ8Ø6	
323.0	Ø. Ø1411	
339.0	0.04952	
355.Ø	0.089 50	
371.0	0.12206	
387.0	0.14284	
403.0	Ø. 15546	
419.0	Ø.16246	
435. Ø	0.16712	
451.0	0.16945	
467.0	0.17105	
483.0	0.17211	
499.0	0. 17253	
515.0	Ø. 17317	
531.0	0.17338	
547.0	0.17391	
563.0	0.17370	
579.0	0.17401	
595.0	0.17391	
611.0 627.0	0.17412 0.17433	
007.0	v.1/400	A_05132C

Figure E-12b. Absorbance vs Time Table (Page 2 of 2)

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Appendix F QUALITY CONTROL REPORTS

14 Jun 95 12:21:58 PAGE 1

Lakeview General Hospital Critical Care Unit Building 1 1224 Toledo Avenue Lakeview, CA 97111-0000

CONTROL: SYNCHRON 3

LOT: M402103

RUN DATE/TIME: Jun 14 95 12:03

SAMPLE ID: SYNCHRON3

SECTOR: 2 CUP: 3

SAMPLE TYPE: Serum DILUTION: 1.0

CHEM	LOC	LOT	S/N	RESULTS	UNITS	CONTROL RANGE	REMARKS/FLAG
BUN3		N/A		59	=g/dL	55.0 - 67.0	
GLU3		N/A		364	∎q/dL	360.0 - 412.0	
CRE3		N/A		7.9	#q/dL	7.40 - 8.60	
TP3	*	N/A		7.9	ŋ√dL	7.00 - 8.40	
ALB	(1)	311223	384	5.0	g/dL	4.40 - 5.60	
ALB	(5)	404234	ØHH	4.9	g/dL	4.40 - 5.60	
CHOL	(4)	401169	0M5	207	#g/dL	209.0 - 249.0	(1) (4)
PHOS	(3)	408025	2YB	7.4	mg/dL	5.60 - 7.80	
CL		N/A		119	ssol/L	115.0 - 127.0	
C02		N/A		31	mmol/L	27.0 - 35.0	
K		N/A		7.7	mmol/L	7.30 - 8.30	
NA		N/A		172	mmol/L	167.0 - 179.0	
CALC		N/A		13.6	#a/dL	11.70 - 13.70	

SAMPLE COMMENTS

INSTRUMENT CODES

FLAGS:

- (1) GREATER THAN 2 SD
- (2) GREATER THAN 3 SD
- (3) MEAN AND/OR SD NOT ASSIGNED
- (4) TWO SUCCESSIVE CONTROLS GREATER THAN 2SD (ACCURACY)
- (5) TWO SUCCESSIVE CONTROLS GREATER THAN 4SD BETWEEN VALUES (PRECISION)

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Figure F-1. QC Report

PAGE 1

QC SUMMARY: Lakeview General Hospital Critical Care Unit Building 1 1224 Toledo Avenue Lakeview, CA 97111-0000

Printed: 15 Jun 95 14:06:45

CONTROL: SYNCHRON 2 LOT: M402102 TYPE: Serum

START DATE: 1 Jun 95 END DATE: 15 Jun 95

			SUMMAI	RY			CUMULATIVE	SUMMARY	
FILE									
NO	CHEM	N	MEAN	SD	CV	N	MEAN	SD	CV
201	ALB	4	3.58	0.05	1.4	4	3.58	0.05	1.4
202	BUN3	3	32.0	0.0	0.0	3	32.0	0.0	0.0
203	CHOL	3	146.3	2.1	1.4	3	146.3	2.1	1.4
204	CL	3	99.7	0.6	0.6	3	99.7	0.6	0.6
205	cos	3	21.0	0.0	0.0	3	21.0	0.0	0.0
206	CRE3	3	4.40	ଡ.ଡଡ	0.0	3	4.40	0.00	0.0
207	CALC	3	9.93	0.06	0.6	3	9.93	0.06	0.6
208	GLU3	3	215.0	1.7	0.8	3	215.0	1.7	0.8
209	K	3	5.10	0.00	0.0	3	5.10	0.00	0.0
210	NA	3	144.0	0.0	ଉ.ପ	3	144.0	0.0	0.0
211	PHOS	3	4.33	Ø. Ø6	1.4	3	4.33	0.06	1.4
212	TP3	, 3	5.80	0.00	0.0	3	5.80	0.00	0.0

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Figure F-2. QC Summary

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		Criti Build 1224	cal Car ing 1 Toledo	eral Hospit e Unit Avenue 97111-000		PAGE 1
QC LOG		Printe	d: 15 J	un 95 1	4:01:11	
\$	START DATE:	1 Jun	95		END DATE: 15	Jun 95
CONTROL:	SYNCHRON 2		LOT:	M402102		TYPE: Serum
ASSIGNED I	JMBER: MEAN: +/-1 SD:	3.7		CUMULA	TUENT CODE: TIVE MEAN: TIVE SD:	3.58 0.05
Date	Time	Result	Unit	Flags		Comments
14 Jun 95	12:38	3.6	g/dL g/dL			
BUN3 QC FILE N ASSIGNED I ASSIGNED ·	JMBER: MEAN: +/-1 SD:	202 33 2.0		CUMULA	TUENT CODE: TIVE MEAN: TIVE SD:	32.0 0.0
Date	Time	Result	Unit	Flags		Comments
14 Jun 95 13 Jun 95 12 Jun 95	14:50	32 32 32	mg/dL mg/dL			
	UMBER: MEAN: +/-1 SD:			CUMULA	TUENT CODE: TIVE MEAN: TIVE SD:	
Date	Time	Result	Unit	Flags		Comments
14 Jun 95 13 Jun 95 12 Jun 95	12:41	148 147 144	mg/dL	2SD	15Jun95002	W/In 3SD, SYN : &3 and Prev OK

Figure F-3. QC Log

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	QC (CHART		PAGE	1
)]	_akeview Genera Critical Care U Building 1 1224 Toledo Ave Lakeview, CA 9	nit			
Pi	rinted: 16 Jun '	95 13	:35:04		
CONTROL: SYNCHRON 2 CHEMISTRY: ALB		M402102 201		TYPE: Serum JENT CODE:	
START DATE: 12	2 Jun 95	,	END DATE:	16 Jun 95	
	3.20	3.6	4.	00	
	-2 -1	X	+1 +8		g/dL
16 Jun 95 6:57	1	l ×	1		3.7
16 Jun 95 6:57	1	l ×	1		3.7
16 Jun 95 6:54	1	×	İ		3.6
16 Jun 95 6:54	1	к 1			3.7
14 Jun 95 12:17	н ж	1	1		3.5
14 Jun 95 12:17	1	×	I		3.6
13 Jun 95 12:38	1	×	I		3.6
12 Jun 95 9:55	1	×	1		3.6
-3	-2 -1	X	+1 +8	2 +3	
					A_05074C.EPS

Figure F-4. QC Chart

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			PAGE
		QC FILE LIST	
	Pr	inted: 14 Jun 95 13:41:2	7
CHEM	CONTROL	LOT	QC FILE
			GC FILE
BUN3	SYNCHRON 1	M402101	102
BUN3	SYNCHRON 2	M402102	202
BUN3	SYNCHRON 3	M402103	302
BUN3	LYPHOCHEK 1	63601	401
BUN3	LYPHOCHEK 2	63602	501
CL	SYNCHRON 1	M402101	104
CL	SYNCHRON 2	M402102	204
CL	SYNCHRON 3	M402103	304
CL	LYPHOCHEK 1	63601	402
CL	LYPHOCHEK 2	63602	502
605	SYNCHRON 1	M402101	105
CO2	SYNCHRON 2	M402102	205
cos	SYNCHRON 3	M402103	305
CRE3	SYNCHRON 1	M402101	106
CRE3	SYNCHRON 2	M402102	206
CRE3	SYNCHRON 3	M402103	306
CRE3	LYPHOCHEK 1	63601	403
CRE3	LYPHOCHEK 2	63602	503
CALC	SYNCHRON 1	M402101	107
CALC	SYNCHRON 2	M402102	207
CALC	SYNCHRON 3	M402103	307
CALC	LYPHOCHEK 1	63601	404
CALC	LYPHOCHEK 2	63602	504
GLU3	SYNCHRON 1	M402101	
GLU3	SYNCHRON 2	M402101	108
GLU3			208
GLU3	SYNCHRON 3	M402103	308
GLU3	LYPHOCHEK 1	63601	405
	LYPHOCHEK 2	63602	505
K	SYNCHRON 1	M402101	109
K	SYNCHRON 2	M402102	209
K	SYNCHRON 3	M402103	309
K	LYPHOCHEK 1	63601	406
K	LYPHOCHEK 2	63602	506
NA	SYNCHRON 1	M402101	110
NA	SYNCHRON 2	M402102	210
NA	SYNCHRON 3	M402103	310
NA	LYPHOCHEK 1	63601	407
NA	LAbhochek 5	63602	507
TP3	SYNCHRON 1	M402101	112
TP3	SYNCHRON 2	M402102	212
TP3	SYNCHRON 3	M402103	312
			A_05

Figure F-5. QC File List (by chemistry)

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			PAGE 1
QC FILE LIST F	OR SYNCHRON 1		
Printed: 14 J	fun 95 13:4	0:16	
LOT	CHEM	QC FILE	
M402101	ALB BUN3 CHOL CL CO2 CRE3 CALC GLU3 K NA PHOS TP3	101 102 103 104 105 106 107 108 109 110	
			A_05076C.EPS
	Printed: 14 J	LOT CHEM M402101 ALB BUN3 CHOL CL CO2 CRE3 CALC GLU3 K NA PHOS	Printed: 14 Jun 95 13:40:16 LOT CHEM QC FILE M402101 ALB 101 BUN3 102 CHOL 103 CL 104 CO2 105 CRE3 106 CALC 107 GLU3 108 K 109 NA 110 PHOS 111

Figure F-6. QC File List (by control)

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							PAGE 1	
	CX.	7 DELTA COMF	REHENSIVE	CON	TROL LIST	ING		
		Printed: 14	Jun 95	13	:42:06			
CONTROL LOT TYPE	: SYNCHRON : M402101 : Serum	1					, 1950 1950 485 486 486 486 4	allia antipo antika imaka pincipo prepu
CHEMISTRY	UNITS	ASSIGNED MEAN			E RANGE SD)		CNST CODE	
	mg/di mg/di mmol/L mmol/L mg/di mg/di mg/di mg/di mmol/L	108 77 12 0.6 6.9 45 2.5 113	73.0 9.0 0.40 6.30 37.0 2.20 109.0		8.0 123.0 81.0 15.0 0.80 7.50 53.0 2.80 117.0 2.40	104 105 106 107 108 109		

Figure F-7. Comprehensive Control List

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Summary of Quality Control Functions

The Quality Control Program monitors quality control results generated on the CX4CE/CX4 DELTA or CX7/CX7 DELTA. The control program monitors statistics for up to 72 chemistries on fifty different control materials. Control results are evaluated as the instrument is running and rule violations 1-2S and 1-3S are flagged on a real-time basis and displayed on the console monitor. Results greater than 2 SD and greater than 3 SD are flagged with colored notes. Results greater than 4 SD are not used in the calculation of statistics, but are included in the QC Log and QC Chart (Levey-Jennings).

The Quality Control program offers five main functions:

- QC Action Log —provides results for a specified period and relates each result to the assigned mean, SD and preceding result in the control file. The Westgard Rules applied in the QC Log are 1-2S, 1-3S, 2-2S, and R-4S. The flags generated as a consequence of comparison to a preceding result are Accuracy and Precision. For an explanation of the flags and how they are determined by the analyzer, refer to the paragraph in this Appendix entitled "Determination of QC Flags." Operators may select data points for action log comments and/or deletion from statistical QC Calculations.
- QC Summary —eontains the mean, SD, CV and number (N) of results for any control run within a specified
 date interval. Cumulative statistics are also provided. The QC Summary may be printed in a CAP format
 with the CAP ID number and CAP Attention Person designation.
- QC Chart (Levey-Jennings) —plots the results in a control for a specified period (typically one month), showing the position of each data point relative to the assigned mean and SD.
- Archive QC -archives up to 25,000 data points to a floppy disk for future retrieval/review.
- Program and Host Setup —provides ability to set system to program QC by chemistry or reagent cartridge and whether or not to send QC results to the host.

Determination of QC Flags

SYNCHRON CX4CE/CX4 DELTA and CX7/CX7 DELTA use the Z-score method for standardizing the scale of a normally distributed measurement variable. For an individual control result, the Z-score represents the distance in standard deviations from the assigned mean. The Z-score is calculated from the following equation:

$$Z = \frac{(x - \bar{x})}{SD}$$

Where X = the individual control result

 \overline{X} = the assigned mean for the control

SD = the assigned standard deviation for the control

Each time a control result is received, the Z-score is calculated. If the Z-score is less than \pm 2, the result is within the assigned control range (the assigned mean \pm 2 assigned standard deviations) and is considered acceptable.

Flags Generated

1-2S: Result Between ± 2SD and ± 3SD From the Assigned Mean

If the result is between \pm 2 and \pm 3 standard deviations from the assigned mean, the result is flagged as > 2SD on the QC Log report, appears in yellow on the QC LOG and QC CHART Screens, and is highlighted in a pop-up note on the monitor as the system is running.

1-3SD: Result Greater Than 3SD From the Assigned Mean

If the Z-score is greater than \pm 3 SD from the assigned mean, the result is flagged "> 3SD" on the QC Log report, and appears in red on the QC LOG and QC CHART Screens, and is included in a real-time pop-up window as the system is running.

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"Accuracy" and "Precision" Flags

2-2S and R-4S: Results Between 2 SD and 3 SD as Compared to the Previous Result

In addition, the Z-score for the current result is compared with the Z-score of the previous result in the same QC file. If both Z-scores are beyond 2 SD on the same side of the assigned mean, the current result receives an "Accuracy" flag on the QC Log report; this flag signifies a violation of the 2-2S rule. If the two results being compared are greater than 2 SD on opposite sides of the assigned mean, the current result receives the "Precision" flag on the QC Log report, signifying a violation of R-4S rule.

Results Greater Than 4 SD From the Assigned Mean

Results greater than 4 SD are included in the QC Log and QC Chart, but are not used to calculate statistics.

Flags Generated on Printed QC Reports

- 1. Greater than 2 SD
- 2. Greater than 3 SD
- 3. Mean and/or SD not assigned
- 4. Two successive controls greater than 2SD (Accuracy)
- 5. Two successive controls greater than 4SD between values (precision)

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TIMED URINE RESULTS REPORTS FOR CX4/CX7

When an operator designates Timed Urine as the sample type for a sample ID, the results report will reflect both the concentration of the aliquot placed on the instrument, and the concentration of the analyte with respect to sample volume and collection time period. CX7 performs additional calculations to accurately report the concentration as a function of volume and time.

Constants and Factors Involved

The sample volume will always be expressed in milliliters.

The selectable units for any given chemistry are always expressed as weight per milliliter (therapeutic drugs only and this would be extremely rare), deciliters or liters. Therefore, the factors applied to total volume will only be:

milliliters to milliliters = 1.0
milliliters to deciliters = 0.01
milliliters to liters = 0.001

Example #1: Timed Urine

An example of results calculations for a chemistry expressed in mg/dL is given with the resulting report.

A Calcium is requested on a timed collection specimen of urine. When an aliquot of the sample is tested on the CX7, a result of 10.8 mg/dL is obtained. In Sample Programming the operator entered a total volume of 1,480 mLs, and a total collection time of 23.5 hours in sample programming.

- 1. Convert the mLs used to express volume to dL by multiplying the total volume 1,480 times 0.01 for an adjusted total volume of 14.80 dL.
- 2. Multiply the Calcium result by the volume.
 - $10.8 \text{ mg/dL} \times 14.80 \text{ dL} = 159.8 \text{ (mg)}$

3. Express the result as a function of the collection period. (See Figure G-1).

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17 Aug 95 10:31:54 PAGE 1

A 05153C.EPS

Lakeview General Hospital 1224 Toledo Avenue Lakeview, CA 97111-0000

NAME: JOHNSON, MARY J. SAMPLE ID: 0253126
PATIENT ID: 555-33-6666 SAMPLE TYPE: Timed Urine

AGE: 35 years DOCTOR: MARTIN
DATE OF BIRTH: Feb 2 60 DRAW DATE/TIME: Aug 17

DATE OF BIRTH: Feb 2 60 DRAW DATE/TIME: Aug 17 95 6:00 SEX: F RUN DATE/TIME: Aug 17 95 10:29 LOCATION: 234A SEC/CUP/REP: 10/1

LOCATION: 234A SEC/CUP/REP: 10/1
PAT. COMMENT:

SAMPLE COMMENT: URINE REFRIGERATED FOR 12 OF 24 HOURS

INST CODES:

CHEMISTRY RESULTS UNITS REFERENCE RANGE REMARKS

NA 76 mmol/L 40 - 820

TIMED URINE PARAMETERS

TOTAL COLLECTION TIME: 24.0 hours TOTAL VOLUME: 1850.0 m1

CALCULATED VALUES RESULTS UNITS REFERENCE RANGE REMARKS

NA 140.60 mmol/24.0 hrs

Figure G-1. Timed Urine Report

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Example #2: Creatinine Clearance

When Creatinine is ordered on a timed urine sample, three results are generated: the concentration of creatinine in the aliquot, the concentration as a function of time and volume (calculated like any other timed urine), and the creatinine clearance result. The aliquot result is reported in the regular results area of the report. The concentration per time and the clearance rate are reported in the section headed Calculated Values.

Creat Clearance = [(U * V) / P] * (1.73 / A) where

U = urine creatinine value, determined by analysis

V = total volume of the sample in mLs per unit of time, input by operator

For Creatinine Clearance (1), the unit of time is minutes For Creatinine Clearance (2), the unit of time is seconds

P = serum creatinine value, input by operator

A = estimated body surface of patient, operator input

1.73 = constant factor used to normalize body surface

Collection time = entered in hours by operator

Given a timed urine sample, a creatinine is performed on an aliquot of that sample. The units selectable for Creatinine are mg/dL, mg/L, mmol/L and umol/L; therefore, the instrument will temporarily convert the units selected in mg/dL is not used. As an example, assume the following:

U = 30 mg/dL

V = 1480 mLs, instrument converts to 14.8 dL

P = 1.0 mg/dL

A = 1.45

Collection time = 24 hrs; instrument multiplies 24 hours by 60 minutes to get 1440

minutes (if instrument is set to report in mLs/sec, the hours are

multiplied by 3600 seconds)

Calculating the Timed Urine Creatinine and Clearance Rate

Step 1: U * V = 30 mg/dL * 14.8 dL = 444 mg

This is the concentration of creatinine per time.

Step 2: UV/P = 444 mg / (1.0 mg/dL) = 444 dL

Step 3: (UV/P) * (1.73/1.45) = 444 dL * 1.19 = 529.74 dL

Step 4: Convert dL to mL 529.74 dL = 52,974 mL

Step 5: Divide volume by # minutes in collection period (1440).

Step 6: 52,974 mLs/1440 min = 36.79 mLs/min cleared

This is the Creatinine Clearance result.

Notes to the Operator:

- 1. The surface area correction factor (1.73/A) is ignored if a value of zero is entered in the surface area field.
- 2. If a serum Creatinine result in not entered, the resultant Creatinine Clearance will indicate "ONE OR MORE CHEM RESULTS NOT AVAILABLE".
- 3. Surface area normalization will be applied if the area is entered with a value greater than zero.
- 4. If a zero result is entered in the Collection Time field, an error will be flagged.
- 5. If the ENTER key is pressed in the surface area field without entering a value, a value will be used in the calculation to set the surface area correction factor to "one".

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17 Aug 95 11:10:09 PAGE 1

A 05154C.EPS

Lakeview General Hospital 1224 Toledo Avenue

Lakeview, CA 97111-0000

NAME: JOHNSON, MARY J. SAMPLE ID: 0253225 PATIENT ID: 555-33-6666 SAMPLE TYPE: Timed Urine

AGE: 35 years DOCTOR: MARTIN

DATE OF BIRTH: Feb 2 60 DRAW DATE/TIME: Aug 17 95 RUN DATE/TIME: Aug 17 95 10:29 SEX: F

LOCATION: 234A SEC/CUP/REP: 10/2

PAT. COMMENT: SAMPLE COMMENT: URINE REFRIGERATED FOR 12 OF 24 HOURS

INST CODES:

CHEMISTRY RESULTS UNITS REFERENCE RANGE REMARKS

42.6 mg/dL 10.0 – 400.0

TIMED URINE PARAMETERS

TOTAL COLLECTION TIME: 24.0 hours TOTAL VOLUME: 1850.0 ml SERUM CREA: 1.5 mg/dL

BODY SURFACE AREA: 1.93 m2

CALCULATED VALUES RESULTS UNITS REFERENCE RANGE REMARKS

CRE3 788.10 mg/24.0 hrs CREA CLEAR:CRE3 32.71 mL/min

75.00 - 135.00 LOW

Figure G-2. Creatinine Clearance Report

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1. KEY TERMS

The following key terms are used throughout this document and in the barcoding industry.

Bar: A strip (or element) whose reflectance is at a minimum, usually black.

Barcode symbol: A group of parallel bars and spaces whose widths encode characters. A barcode symbol typically contains a leading quiet zone, a start character, data characters, a check character, a stop character and a trailing quiet zone.

Character: The smallest group of elements that represents a number, letter, or punctuation mark.

Check Character (or digit): A character which is used to mathematically check that the code symbol was read correctly.

Element: Either a bar or space in a barcode symbol.

Intercharacter Gap: The space that separates two characters. Not present in all symbologies.

Quiet Zone: An area at each end of a barcode symbol, which must be kept clear of any marks, including human readable text.

Self Checking: A barcode that uses a checking algorithm to determine if the barcode symbol was read correctly.

Space: A strip (or element) whose reflectance is at a maximum, usually the white of the label material.

Start and Stop Characters: Characters within a barcode symbol which help delineate the data and determine the scan direction.

Symbology: A set of rules for encoding and decoding information contained in a barcode symbol. Examples of symbologies are Code 39, Code 128, Interleaved 2 of 5, and Codabar.

2. COMMON BARCODE SYMBOLOGIES

CODE 39: (Also known as 3 of 9 and USD-3)

Variable in length.

Recommended for use in alphanumeric labeling.

Includes 43 data characters:

26 letters (Uppercase A-Z); ten digits (0-9), six symbols (. \$/ + % -) and a space.

Strong self checking properties.

Very low frequency of substitution errors: less than 1 in 70 million characters.

Discrete (white spaces not part of code - ability ensures print capability on a wide variety of equipment. Most widely used barcode in industry today.

CODE 128: (Also known as USD-6)

Variable in length.

Alphanumerics; 107 character set.

Self checking.

Continuous code (intercharacter space is part of code structure) offering higher density of code per square inch; compact barcode.

Substitution error frequency: less than 1 in several million characters.

One of the most recent barcode types.

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INTERLEAVED 2 OF 5: (Also known as I2 of 5, USD-1)

Fixed in length.

Numerics only.

Most commonly used without check digit.

Lower density of code per square inch; longer label.

CODABAR: (Also known as USD-4)

Variable in length.

Numerics only; 10 digits, "-"and "\$"signs.

Widely used with check digits.

First accepted in a medical application by blood banks as a standard for coding units.

Lower density of code per square inch; longer barcode.

Substitution error frequency: less than 1 in several million characters.

One of the oldest barcode types.

3. OVERVIEW OF SYSTEM COMPONENTS

The CX4/CX7 barcoding system comprises four major components: a barcode head, decoder board, software, and one or more sectors containing the barcoded primary sample tubes. The barcode head is the device that uses a laser to scan the label. The barcode decoder board contains the circuitry that decodes what the head sees. The system software contains the logic necessary to set up the barcode decoder board and correlate the results to the patient identification. The sector is a primary sample tube holder that contains up to seven barcoded tubes. Each primary sample tube is labeled by the operator. This label assures a one-to-one correspondence between the results and the patient identification.

BARCODE HEAD

The CX4/CX7 contains a scanning barcode head. The barcode head contains a six-sided mirror and a visible light laser diode. As the mirror spins, the laser beam reflects off the mirror and scans the barcode label. The reflected light enters the barcode head and is measured and processed. A visible light barcode head is superior to the infrared light units because it allows for reading a wider variety of label stock materials. In addition, when diagnosing a problem, the operator can see if the beam is turned on and whether it is hitting the right part of the barcode label. The visible light laser is a CLASS II laser device and operators should not stare at the beam for prolonged periods of time.

DECODER

The barcode head output is sent to the barcode decoder board. The barcode decoder board performs more signal processing and decodes the final symbology. The decoder board can be programmed to decode one or more symbologies and each symbology's options. The output from the decoder board is an RS232 serial stream of data that is sent to the computer through the Main Motor Controller board.

SECTORS

A sector is a sample tube holder that can hold up to seven sample tubes. The sector contains two barcode labels of its own. The sector identification label is positioned vertically between position one and two for the CX4/CX7 DELTA systems. It is read by the sample barcode reader. On the CX4CE/CX7 Systems the sector identification label is positioned horizontally at the bottom of the sector. This is read by the sector reader. This label informs the system which sector is loaded in a particular sample carousel position. Another label, the background label, is located on the center portion of the sector and is scanned by the sample cup/tube barcode reader. This label informs the system that a cup/tube is installed in a particular position in a sector. If the system can read the background label, a cup/tube is not loaded in that sector position. If the system cannot read the background label, the cup/tube position is assumed to be occupied by a sample.

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SOFTWARE

This section will give some background as to how the sample barcode reader reads the labels, and guidelines to assist the operator when setting the system up for each type of code. The software sets up the barcode decoder board to read labels with different symbology parameters. The software also initiates what the barcode reads.

When the system is set to run in barcode mode (barcode mode [enabled]), the barcode parameters of the reader are set through the console. Each time the parameters are changed on the barcode screen, the sample barcode reader is sent a message that resets the parameters in the reader.

On CX4/CX7 DELTA systems, when a sector is loaded, the barcode reader identifies the wheel position and sector number, reads the sample tube barcode labels, determines the background barcode label, and identifies any empty cup positions. On CX4CE/CX7 systems the sector reader identifies the wheel positon and sector number. Subsequently, the sample barcode reader reads the sample tube barcode labels, determines the background barcode label and identifies any empty cup positions. The sector passes the sample barcode reader twice. The first pass determines the sample ID and sector/cup position of the samples in the sector. The second pass reads the background barcode label and identifies any empty cup positions. On all systems, in order for the decoder board to identify a sample or the background label, the reader must receive 3 consecutive matching reads to make a positive identification. The reader can then determine whether the label is "good" and transmits the information back to the console. If the barcode label cannot be read by the sample reader, a message appears stating "invalid sample IDs loaded on sector (sector number)". The message also contains a listing of all positions on the sector with a "?" where the label could not be read. See the troubleshooting section for instructions on how to proceed when a sample barcode label cannot be identified.

After the information from the reader is received by the console, the software matches the sample ID and sector/cup position to a programmed sample and the sample is processed. If no match between the sample on the wheel and a programmed sample is determined, a message appears to warn the operator that the sample is not programmed. To ensure positive patient identification, it is vitally important that any programmed sample ID or any assigned calibrator ID matches its barcode label exactly.

The CX4/CX7 sample barcode reader can utilize four different symbologies - Code 128, Code 39, Interleaved 2 of 5, and Codabar. Each symbology has specific parameters and character sets, as described in section 2, Common Barcode Symbologies. However, invalid Sample ID characters on the SYNCHRON CX Systems include *, ?, \$, space, comma, and semi-colon. Alpha characters MUST be entered in UPPER case when using Code 39.

4. BARCODE LABELS

This section describes the type of sample tube label required. Operators are responsible for generating their own labels and for applying them to the tube. There are several industry standards to assist the operator in barcoding which are outlined here.

4a. Industry Standards

The industry has generated several different types of bar symbologies. Each symbology was created by different industries, for specific purposes, but most were standardized by the American National Standards Institution (ANSI). Copies of each standard can be obtained from ANSI (see Reference section). Each symbology also has options which can be incorporated into the barcode label. Options include check characters and start and stop characters. These options help improve the read rate accuracy by eliminating substitution errors. Using a symbology without check characters increases the probability of short reads and character substitutions; this defeats the purpose of having positive sample identification in the medical industry. A check character should always be used.

Another standards group is the American Identification Manufacture's group (AIM). They are a manufacturers' consortium which is promoting barcoding, and currently presides over the Code 128 symbology.

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A group under the American Society for Testing Materials (ASTM) was formed to deal with barcoding in the clinical laboratory. ASTM has since released their own barcode requirements (see Reference section).

Beckman recommends following the ASTM or AIM standards where possible. This provides the maximum compatibility with other analyzers that use barcoding.

4b. CX4/CX7 Label Requirements

A. Label Size

The overall length of the label shall not exceed 2.35 inches (per ASTM standards). This length will include the barcode symbol and a minimum quiet zone of 0.20 inches at each end of the symbol.

B. Symbol Content

The barcoded sample ID may contain up to 11 characters. For acceptable characters see the CX4/CX7 Operating Instructions, section 6.4. Current recommendations call for the symbol content to be printed on the label in human readable form. This is useful if the symbol becomes damaged and the operator has to hand enter the barcoded information.

C. Feature Size

The narrow element width shall be nominally 0.0075-0.02 inches.

D. Label Orientation and Placement

The labels shall be placed so that the bars follow one another down the tube. The barcode reader scans the tube vertically. Use this 'ladder' placement and not a 'fence' placement. The label should not be skewed more than ± 1 -5%.

The top of the label should be within 0.2 inches of the rim of the tube or skirt of the cap.

The tubes must be placed in the sector such that the symbol is exposed through the front slot of the sector. The entire symbol, including the quiet zone, must be visible through the slot and above the base of the sector when viewed at eye level.

E. Check Characters

The use of check digits and fixed length codes is highly recommended where possible. This greatly reduces the possibility of scanning errors.

F. Label and Print Quality

The minimum acceptable symbol grade is class 'C' as defined in the ANSI Print Quality Specification (see Reference section). The measure of such quality is done at 900 nanometers wavelength with a 0.005 inch aperture.

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G. Label Sources

All labels are supplied by the customer. Preprinted labels can be used, or labels generated by a barcode printer. Because a visible light scanner is used, direct thermal or thermal transfer printing methods may be used.

Although labels printed on impact and laser jet printers do work, they usually do not meet ANSI specifications, and thus cannot be recommended by Beckman. Beckman does recommend the following printers:

Execuport 2400 MedPlus

8600 Governor's Hill Dr.

Suite 112

Cincinnati, OH 45249 Phone (800) 444-6235

(513) 583-0500

Intermec 3000A Intermec Corporation

6001 36th Avenue West Everett, Washington

98203

Phone (800) 755-5505 (206) 348-2600

Zebra 130 Zebra Technologies Corp

333 Corporate One Parkway

Vernon Hill, IL 60061 Phone (800) 423-0422 (708) 634-6700

Please contact any of the above vendors or Industry Standard associations for any specific barcode application issues.

4c. Label Suggestions

There are many options available when making up barcode labels. Each situation may have particular requirements. Listed below are some guidelines to assist the operator in designing barcode labels for use with the CX4/CX7.

- Use Code 39 or Code 128 with a fixed length and check digits.
- Make the symbol height on the label approximately 3/4" on a 1" wide label stock. Be sure to leave enough space for any human readable information on the label. Since tubes may rotate within the sector, the 3/4" symbol height will help to avoid misreads due to label rotation.
- Use .0075 inch wide narrow elements and a 2.5:1 ratio wide elements to narrow elements.

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5. SOFTWARE SETUPS

The CX4/CX7 supports several barcode parameters. The default software settings are listed below:

Symbology	Options	Default Setting
Code 39	Check Digit Large Intercharacter Gap Fixed Code Length Code Length	enabled (cannot be disabled) disabled disabled disabled {10 }
Interleaved 2 of 5	Check Digit Code Length One Code Length Two	enabled disabled {10 } {6 }
Codabar	Large Intercharacter Gap Fixed Code Length Code Length Start/Stop Codes Match	enabled disabled disabled {10 } disabled
Code 128	Fixed Code Length Code Length	enabled (cannot be disabled) disabled {10 }

Each parameter is designed in a specific way and the software treats each differently. These are some "tips" which will assist the operator in setting the system up to read the sample labels correctly.

General notes for symbologies

- Be careful not to mix zeros (0) and the letter O as they may look almost identical.
- When Fixed Code Length is disabled and the default setting for the code length then changes to {10 },
 this means that the sample reader will read code lengths up to 10 characters long, not that the code
 must be 10 characters long. When fixed code length is enabled and the code length set, the sample
 reader will only read codes which have the set number of characters. Please check the next few notes
 to see how the final code length is determined for each type of symbology when check digit is enabled
 or disabled.
- Although both Code 39 and I 2 of 5 have the check digit capability, when determining the fixed code length for either this parameter is treated differently. Code 39 and I 2 of 5 expects the check digit to be excluded in the final code length. That is, if the sample ID is 5 characters long with a check digit, the fixed code length with check digit enabled is 5.

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Interleaved 2 of 5

- Code I 2 of 5 requires that the final code length, with check digit or with no check digit must be an even number of characters. The CX4/CX7 software will only allow odd number code lengths (excluding the check digit) to be read when check digit is enabled and only even number code lengths when check digit is disabled.
- When the check digit enabled mode is used for I 2 of 5, the maximum value accepted is nine (9), even though the message window instructs the operator to enter odd numbers from 1 to 11.
- It is recommended to run the second code length set to {0} when running I 2 of 5. This code can possibly truncate the longer code length ids and read only a portion of the code if the labels are damaged or do not meet specifications. Setting the second code length to {0} prevents the label from reading if the larger code length cannot be read.

Code 39

- Make Code 39 labels with only upper case characters.
- Code 39 is a self checking symbology. Enabling check digits enhances selfchecking.
- Code 39 cannot use a code length of one at any time.

Codabar

- The intercharacter gap for Codabar is not operational.
- · Codabar cannot use a code length of one at any time.
- If the Start/Stop character option is disabled, both matching and non-matching codes are read. If enabled, the system reads only matching codes. There is no way to exclusively read non-matched codes.

Code 128

• There are no setup exceptions. It is always enabled.

6. TROUBLESHOOTING

Barcode labels which cannot be read by the sample barcode reader appear in an "invalid sample ID" message as question marks in the appropriate sector cup position.

Golden Barcode Standard

An envelope containing test barcode labels is in the CX4/CX7 ship kit. Place one of these labels on an unused primary sample tube. Ensure that the long dimension of the label runs down the length of the tube. Also ensure that the top of the label is within 0.2 inches of the top of the tube. The Golden Barcoded Tube is a diagnostic tool for troubleshooting problems. Keep it in a safe place and take care not to scratch the label.

Another troubleshooting aid is to print extra labels when the instrument is first installed. These labels can then be saved and used as test labels if a problem arises.

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Troubleshooting Procedure:

First ensure that the correct barcode symbology and options are enabled for the code type you are using. Refer to section 6.5 of the CX4/CX7 Operating Instructions. Also verify that the correct symbology character set and only legal characters for the CX4/CX7 are used in the sample ID.

Next ensure that the label is placed properly on the tube and that the tube is properly seated in the sector. Verify that the barcode is visible through the sector slot and the quiet zone is visible above the base of the sector.

Finally, inspect your label for scratches, voids, and other defects.

Clean the barcode window as per CX4/CX7 Operating Instructions, section 9.4.

If your label still does not read, try reading the "golden barcoded tube".

If it reads:		If it does not read:
1.	Try another label.	Ensure the red laser light comes on.
2.	Check your printer.	Call Customer Clinical Support, or your local Beckman representative.

- 3. Print labels by some other means.
- 4. Call Customer Clinical Support, or your local Beckman representative.

7. REFERENCES

SYNCHRON CLINICAL SYSTEMS CX4/CX7 DELTA and CX4CE/CX7 Operating Instructions (P/N 248408) SYNCHRON CLINICAL SYSTEM CX4/CX5/CX7 DELTA and CX4CE/CX5CE/CX7 Diagnostics and Troubleshooting Guide. (P/N 248547)

"Bar Code Symbols on Transport Packages and Unit Loads," ANSI MH 10.8M 1983, American National Standards Institute, Inc.

"Standard Specifications for the Use of Bar Codes in Clinical Laboratory Specimen Management." Draft, American Society for Testing Materials.

"Bar Code Print Quality Guidelines." ANSI X3.182 1990, American National Standards Institute, Inc.

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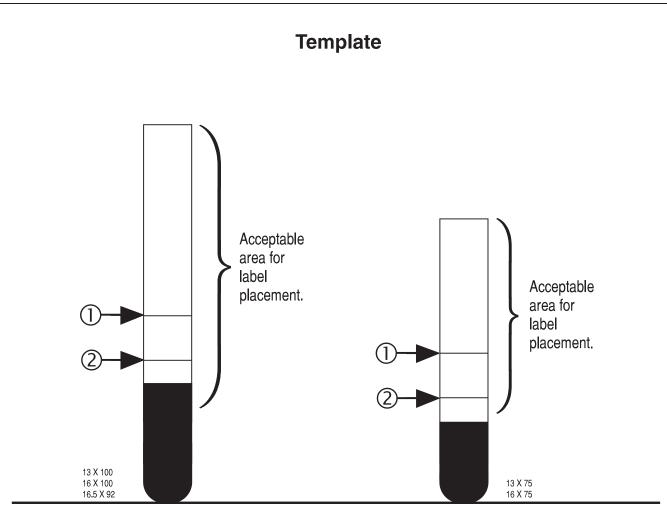
General Precautions for Sample Preparation

- 1. Always wear gloves when handling patient samples, control materials or any serum based material.
- 2. Avoid contamination of the sample or sample tube/cup with talc, aerosols of salivary amylase, or oils, salts, lotions from the skin.
- 3. Verify that the sample is free of visible fibrin or clots.

Sample Tubes and Sample Requirements

- 1. Primary Sample Tubes
 - (a) Tube Sizes: 13 x 100 mm, 16 x 100 mm, 16.25 x 92 mm, 13 x 75 mm, 16 x 75 mm
 - (b) Bar code labels should be placed on the tube so that bars are stacked top to bottom, or bottom to top, perpendicular to the length of the tube. The label does not need to be perfectly straight, but the beam from the bar code reader should be able to scan through a portion of each line in the bar code.
 - (c) Sample Meniscus —Refer to the template (Figure I-1) for determination of adequate meniscus height. All measurements are from the bottom of meniscus. To allow for a minimum of 264 μL of sample for testing and sample excess for proper level sensing, perform the following steps:
 - i. Verify minimum serum/plasma height by aligning the bottom of the tube with the black line under the tube. Total volume level must be higher than or equal to line labeled 1.
 - ii. Verify minimum sample above non-sample. Non-sample is defined as red cells, gel separator or glass beads. Align the top of the non-sample with line labeled 2. The serum/plasma level must be higher than or equal to line labeled 1.
 - iii. Meeting the requirements for minimum serum/plasma height (Step 1) and minimum sample height above non-sample (Step 2) provides 264 μL of sampling capability.

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A_00146C.EPS

All measurements are from the bottom of the meniscus.

TO VERIFY ACCURATE SAMPLE HEIGHT, PERFORM THE FOLLOWING STEPS:

1. VERIFY MINIMUM SERUM/PLASMA HEIGHT

Align the bottom of the tube with black line on template. Total volume level must be higher than or equal with line 1.

2. VERIFY MINIMUM SAMPLE HEIGHT ABOVE NON-SAMPLE

Non-sample is red cells, gel separator or glass beads. Align top of non-sample with line 2.

Serum/plasma level must be higher than or equal with line 1.

This allows for 264 μ L of sample for testing and sufficient sample excess for proper level sensing by the sample probe.

Figure I-1. Template

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2. Microtubes

- (a) Fits in 13 x 100 mm sector only.
- (b) Bar code labels should be placed on Microtubes the same way that labels are placed on primary sample tubes. Refer to Appendix I, Primary Sample Tubes, Step B.
- (c) Minimum volume requirements:

GLU3, TP3, CA3, BUN3 or CRE3 (1 only) 80 μ L Electrolytes (any/all) 110 μ L All CX3 chems 190 μ L TP3 (CSF) 140 μ L TP3, GLU3, CL (all CSF) 240 μ L

CX4 tests 60 µL dead volume + test volume

3. Sample Cups

- (a) Available sizes are 0.5 mL and 2.0 mL.
- (b) Minimum volume requirements:

	<u>0.5 mL</u>	<u>2.0 mL</u>
TP3, CA3, BUN3, or CRE3 (1 only)	80 μL	150 μL
GLU3	110 μL	150 μL
Electrolytes (any/all)	110 μL	275 μL
All CX3 chems	210 μL	300 μL
TP3 (CSF)	160 μL	160 μL
TP3, GLU3, CL (all CSF)	*	250 μL
CX4 Tests	40 μL dead volume + test volume	175 μL dead volume + test volume

^{*} Not recommended for 0.5 mL cups.

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TEST VOLUME REQUIREMENTS

To determine the minimum volume needed for any group or panel of tests, the recommendations are as follows:

CX3 tests only — Use the minimum volume cited in Steps 1 and 2 above for primary sample tubes and Microtubes. For sample cups use the minimum volume cited in Step 3.

CX4 tests only — Use the template (Figure I-1) for primary sample tubes (minimum sample height provides 264 μ L of sample for testing). For samples requiring serum volume beyond 264 μ L, refer to the chart on page I-4 for individual test volumes (in μ L). For samples run in Microtubes or sample cups, use the appropriate dead volume and add the test volume as appropriate based on the chart on page I-4.

CX3 and CX4 — For Primary sample tubes, use the template (Figure I-1) to determine the minimum sample height which will provide 264 μ L of sample volume; if panel requires more than 264 μ L of sample, refer to the chart on page I-4 for additional volume required. For Microtubes and sample cups, refer to Steps 2 and 3 above and first satisfy the CX3 requirements, then add volume (in μ L) for CX4 tests using the chart on page I-4.

CHEM.	<u>VOL.</u>	CHEM.	<u>VOL.</u>	CHEM.	<u>VOL.</u>	CHEM.	<u>VOL.</u>
ALB	3	CK-	12	lgM	20	PROX	10
ALC	3	CKMB	24	IRON	25	RF	6
ALP	5	CKNa	10	LAC	3	SAL	4
ALPd	5	COCM	20	LAP	20	T4	9
ALT	23	CR-T	20S/3U	LDH	5	TBIL	8
ALT-	23	CREA	20S/3U	LD-L	13	TG	3
AMM	25	CRP	10	LD-P	5	TG-B	3
AMPH	20	DBIL	10	LIPA	4	THC	20
AMY	12	DIG	16	METD	10	THC2	20
ASO	3	FE	25	METQ	10	THC5	25
ASO-	6	GEN	3	MG	3	THE	3
AST	23	GENT	3	M-TP	5CSF/10U	THEO	3
AST-	23	GGT	13	OP	20	TIBC	25
BARB	10	GLU	3	PAMY	10	TOB	3
BENZ	20	GOT	23	PCP	20	TOBR	3
BUN	3	GPT	23	PHE	3	TP	6
CA	3	HBDH	5	PHNB	3	TRF	10
CAR	3	HDLC	5	PHNY	3	TU	15
CHE	3	IBCT	25	PHOS	4	UREA	3
CHOL	3	IgA	8	PHY	3	URIC	12
CK	13	IaG	4	PO4	4	VPA	3

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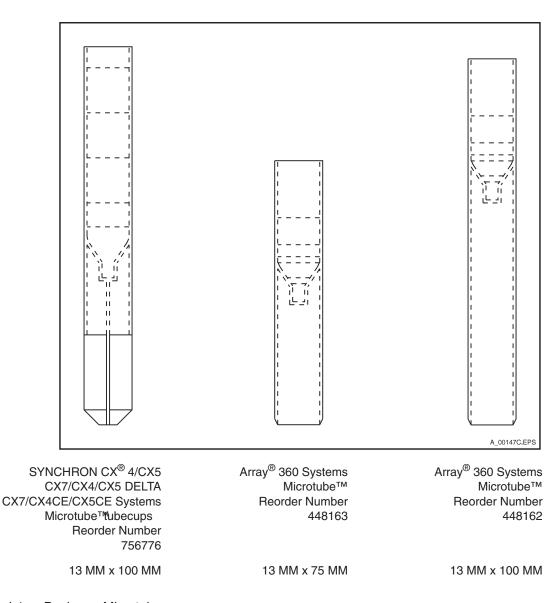


Figure J-1. Beckman Microtubes

Beckman Microtubes are designed for use on specific Beckman Systems. Using the appropriate Microtube is essential for proper system operation. The sample height in the Microtube is critical for correct sample aspiration on all Beckman Systems.

The use of Array[®] Microtubes (P/N 448163 or P/N 448162) on SYNCHRON Systems or the use of SYNCHRON Microtubes (P/N 756776) on Array systems may result in short sampling, incorrect results, and/or sample probe damage.

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The use of non-Beckman, third party Microtubes, which have not been designed and tested on Beckman Systems may result in system damage and/or short sampling.

It is recommended that this notice be posted in the sample processing area in order to ensure correct Microtube usage.

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APPENDIX K Troubleshooting Chemistry Flags

Chemistry Flags

Introduction

All reactions are checked against chemistry parameter flag limits (e.g., Absorbance limits, reference ranges) to qualify the reagent, calibration, or sample. Checks are performed against the final result and on interim reaction data for all samples, including calibrators. Any calibrator or sample result or reaction step performing outside of any one or more limits will be flagged (message or remark). A flagged sample value will not be reported.

Flag Abbreviations for Reports

Table K.1 lists the flag abbreviation and the flag name that appears on the calibration or result report.

Table K.1 Flag Abbreviations for Reports

Abbreviation ^a	Name
BACK TO BACK	Back-to-Back
BL ABS HI (BH)	Blank Absorbance High
BL ABS LO (BL)	Blank Absorbance Low
BL MEAN DEV (BN)	Blank Mean Deviation
BL MAX DEV (BO)	Blank Max Deviation
BL RATE HI (SH)	Blank Rate High
BL RATE LO (SL)	Blank Rate Low
DAC	Digital to Analog Conversion
OCR HI	Out of Calibrator Range High
OCR LO	Out of Calibrator Range Low
REF DRIFT (DR)	Reference Drift
ERRATIC ADC (EA)	Erratic ADC
INT ABS HI (AH)	Initial Absorbance High
INT RATE HI (IR)	Initial Rate High
INC DATA	Inconsistent Data
MATH ERR 5	Calibrator Order Error for Multipoint Chemistry
MATH ERR #	Math Error/Nonoverrideable

(Sheet 1 of 2)

Table K.1 Flag Abbreviations for Reports, continued

Abbreviation ^a	Name
MATH ERR #	Math Error/Overrideable
NOISE (NT)	Noise Threshold
OIR ERR	Out of Instrument Electronic Range
OIR HIGH (HI)	Out of Instrument Range High
OIR LOW (LO)	Out of Instrument Range Low
OIR O HIGH (OH)	ORDAC High
OIR O LOW (OL)	ORDAC Low
ORR HIGH (UH)	Out of Reportable Range High
ORR LOW (UL)	Out of Reportable Range Low
ORR OHIGH (UO)	Out of ORDAC Reportable Range High
OUTLIER (OT)	Outlier Threshold
RECOVERY	Recovery
RX ABS HI (HR)	Reaction Absorbance High
RX ABS LO (LR)	Reaction Absorbance Low
RX MEAN DEV (RN)	Reaction Mean Deviation
RX MAX DEV (RO)	Reaction Max Deviation
RX RATE HI (RH)	Reaction Rate High
RX RATE LO (RL)	Reaction Rate Low
SENSITIVITY	Sensitivity
SEV RECOVERY	Severe Recovery
SEV SENSITIVITY	Severe Sensitivity
SPAN	Span
SUB DEPL (SD)	Substrate Depletion
TEMP ERR (TM)	Temperature Error
ADC ERROR	ADC Error

(Sheet 2 of 2)

^a The two letter codes in parentheses are the error codes which are transmitted to the host.

Flag Descriptions

Flag descriptions are summarized in Table K.2.

Table K.2 Flag Descriptions

Flag Name	Flag Description
Blank Absorbance (high/low)	Mean absorbance measured during the reagent blank spin cycles (read window). The units are in Absorbance and will characterize reagent quality.
Blank Maximum Deviation	A single blank absorbance data point obtained during the reagent blank read window deviates more than allowed from the line of regression. The units are in delta absorbance and will check for a constant rate during the blank spin cycles.
Blank Mean Deviation	The average difference between the absorbance readings and the line of regression is greater than allowed. This will check for a constant rate during the blank spin cycles.
Erratic ADCs	The difference between the high and low value of the four reference electrode readings (taken milliseconds apart) has exceeded the limits allowed. Units are in ADCs and are a measurement of noise in the ISE system.
Calibrator Order Error	Occurs in Sector mode when not all calibrator levels are in ascending order (low to high) and/or not all levels reside in the same sector.
Excessive Reference Drift	A CX3/ISE reference electrode measurement for a sample drifted above the reference electrode measurement from the calibration and/or from sample-to-sample and exceeded the limit. The units are in ADCs and are a measurement of CX3/ISE reference electrode drift.
Initial Absorbance High	The reaction absorbance data taken from the first spin cycle after sample inject has exceeded specifications. This is a measurement of sample integrity.
Initial Rate High	The reaction rate data obtained between 2 and 17 seconds after sample inject exceeds specifications.
Noise	During a particular spin cycle, the average difference between an absorbance reading and the line of regression exceeded specifications.
Outlier	During a particular spin cycle, the deviation of a single absorbance reading with respect to the line of regression exceeded specifications.

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Table K.2 Flag Descriptions, continued

Flag Name	Flag Description
Out of Instrument Range (high/low)	The recovered value exceeds the value that the instrument will report.
Out of ORDAC Range (high/low)	A reaction exceeded the range of ORDAC (Over Range Detection And Correction) values that the instrument will report.
Out of Reportable Range (high/low)	The recovered value exceeds the reportable range limits.
Out of ORDAC Reportable Range (high)	A reaction exceeded the high ORDAC reportable range.
Reaction Absorbance (high/low)	The mean absorbance measured during the reaction spin cycles.
Reaction Maximum Deviation	A single reaction absorbance data point obtained during the reaction read window deviates more than allowed from the line of regression. The units are in delta absorbance and will check for a constant rate during the reaction read window.
Reaction Mean Deviation	The average difference between the reaction absorbance readings and the line of regression is greater than allowed This will check for a constant rate during the reaction spin cycles.
Reaction Rate (high/low)	The rate calculated during the reaction read window. Units are in delta Absorbance/minute.
Substrate Depletion	Difference (delta) between the initial absorbance taken after sample inject and the final absorbance data point within the reaction read window exceeds specification.
Temperature	The operating temperature of the system is beyond 0.1℃ from the set point value. All CX4 Chemistry results will be reported with a flag.
ADC ERROR	More that 1 second elapsed between start and end of ADC conversion process.

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